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(54) **PATIENT-SPECIFIC ACETABULAR ALIGNMENT GUIDES**

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See application file for complete search history.

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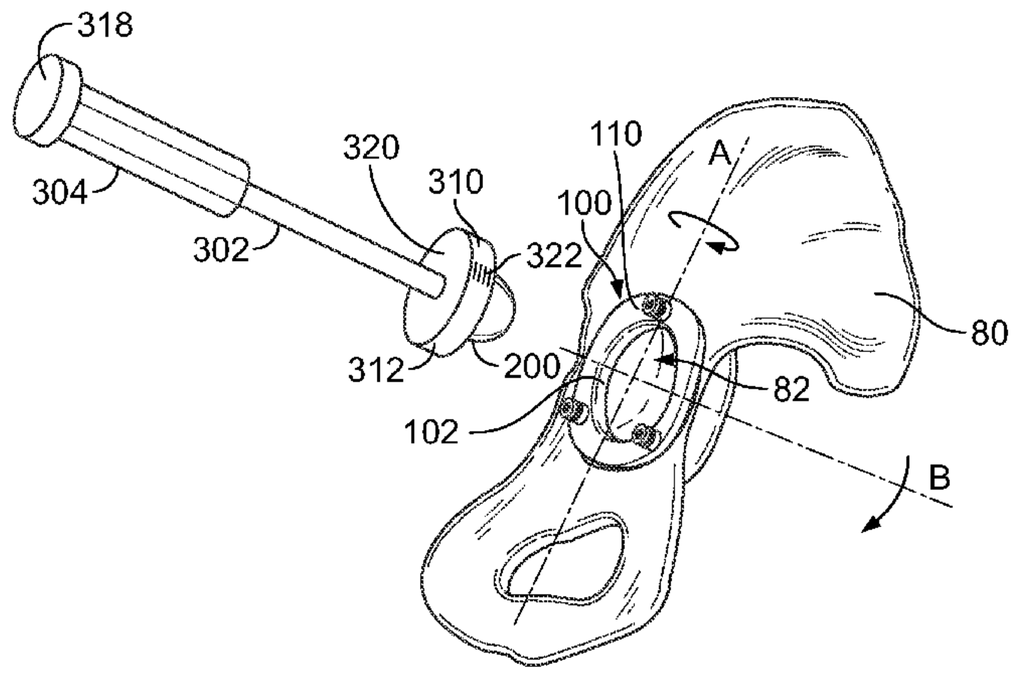
(57) **ABSTRACT**

An acetabular device includes a patient-specific acetabular alignment guide including a bone engagement surface. The bone engagement surface has a first portion configured and shaped to be conforming and complementary to an acetabular rim surface and a second portion configured and shaped to be conforming and complementary to a periacetabular area of an acetabulum of a patient. The acetabular alignment guide includes a plurality of guiding formations extending through the second portion for guiding a plurality of alignment pins therethrough. The bone engagement surface and the plurality of guiding formations are prepared from a three-dimensional model of the acetabulum of the specific patient reconstructed pre-operatively from a scan of the patient.

17 Claims, 19 Drawing Sheets



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continuation-in-part of application No. 12/973,214, filed on Dec. 20, 2010, which is a continuation-in-part of application No. 12/955,361, filed on Nov. 29, 2010, which is a continuation-in-part of application No. 12/938,913, filed on Nov. 3, 2010, and a continuation-in-part of application No. 12/938,905, filed on Nov. 3, 2010, which is a continuation-in-part of application No. 12/893,306, filed on Sep. 29, 2010, which is a continuation-in-part of application No. 12/888,005, filed on Sep. 22, 2010, now Pat. No. 8,377,066, which is a continuation-in-part of application No. 12/714,023, filed on Feb. 26, 2010, now Pat. No. 8,241,293, which is a continuation-in-part of application No. 12/571,969, filed on Oct. 1, 2009, which is a continuation-in-part of application No. 12/486,992, filed on Jun. 18, 2009, and a continuation-in-part of application No. 12/389,901,filed on Feb. 20, 2009, now Pat. No. 8,133,234, which is a continuation-in-part of application No. 12/211,407, filed on Sep. 16, 2008, which is a continuation-in-part of application No. 12/039,849, filed on Feb. 29, 2008, now Pat. No. 8,282,646, and a continuation-in-part of application No. 11/756,057, filed on May 31, 2007, now Pat. No. 8,092,465, said application No. 12/039,849 is a continuation-in-part of application No. 11/971,390, filed on Jan. 9, 2008, now Pat. No. 8,070,752, which is a continuation-in-part of application No. 11/363,548, filed on Feb. 27, 2006, now Pat. No. 7,780,672, said application No. 12/039,849 is a continuation-in-part of application No. 12/025,414, filed on Feb. 4, 2008, now Pat. No. 8,298,237, said application No. 13/111,007 is a continuation-in-part of application No. 12/872,663, filed on Aug. 31, 2010, now Pat. No. 8,407,067, said application No. 13/111,007 is a continuation-in-part of application No. 12/483,807, filed on Jun. 12, 2009, now Pat. No. 8,473,305, which is a continuation-in-part of application No. 12/371,096, filed on Feb. 13, 2009, which is a continuation-in-part of application No. 12/103,824, filed on Apr. 16, 2008, now abandoned, said application No. 13/111,007 is a continuation-in-part of application No. 12/103,834, filed on Apr. 16, 2008, now Pat. No. 7,967,868.

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International Search Report and Written Opinion mailed Oct. 14, 2013 for PCT/US2013/057097 claiming benefit of U.S. Appl. No. 13/597,478, filed Aug. 29, 2012.

* cited by examiner

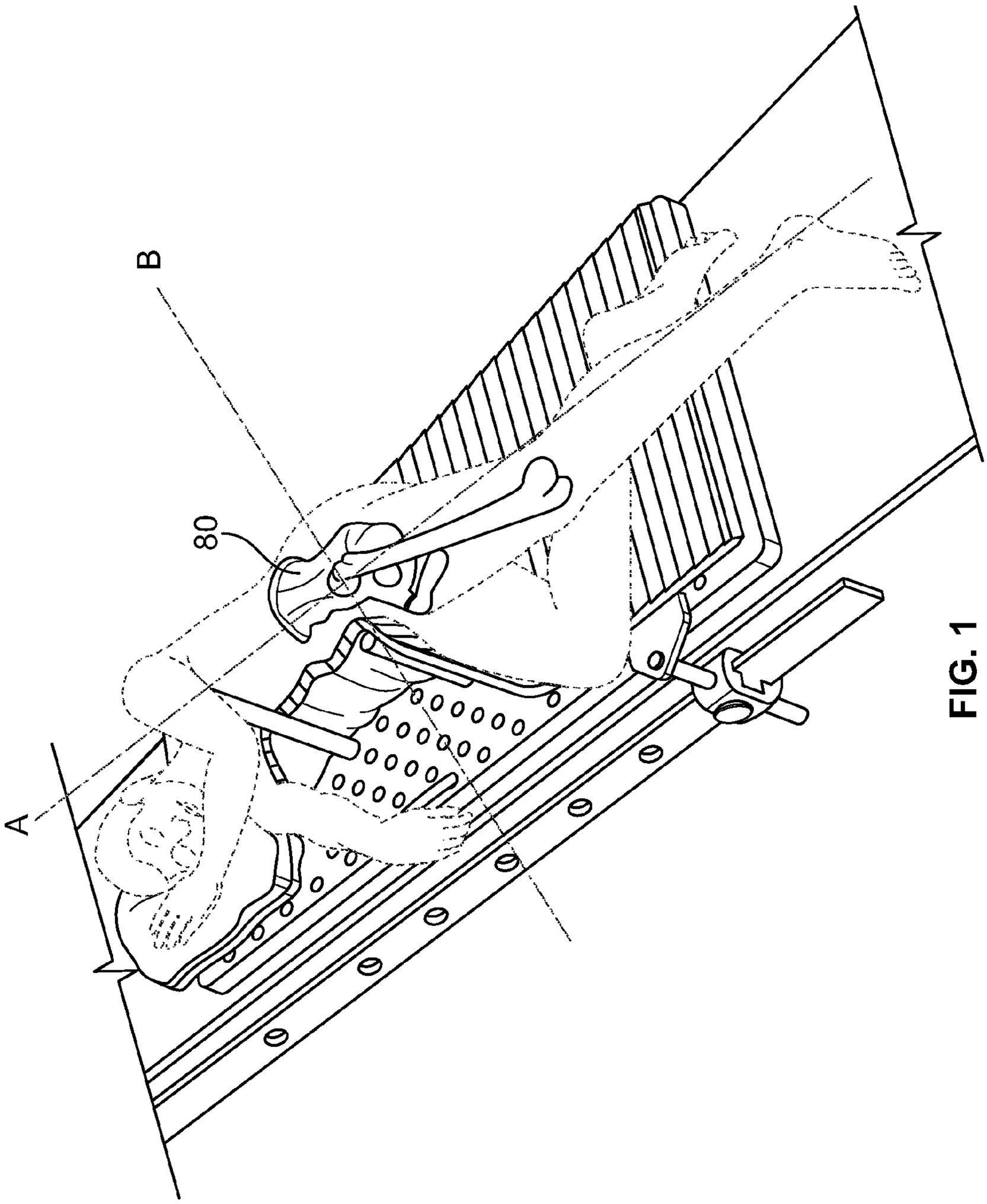

FIG. 1

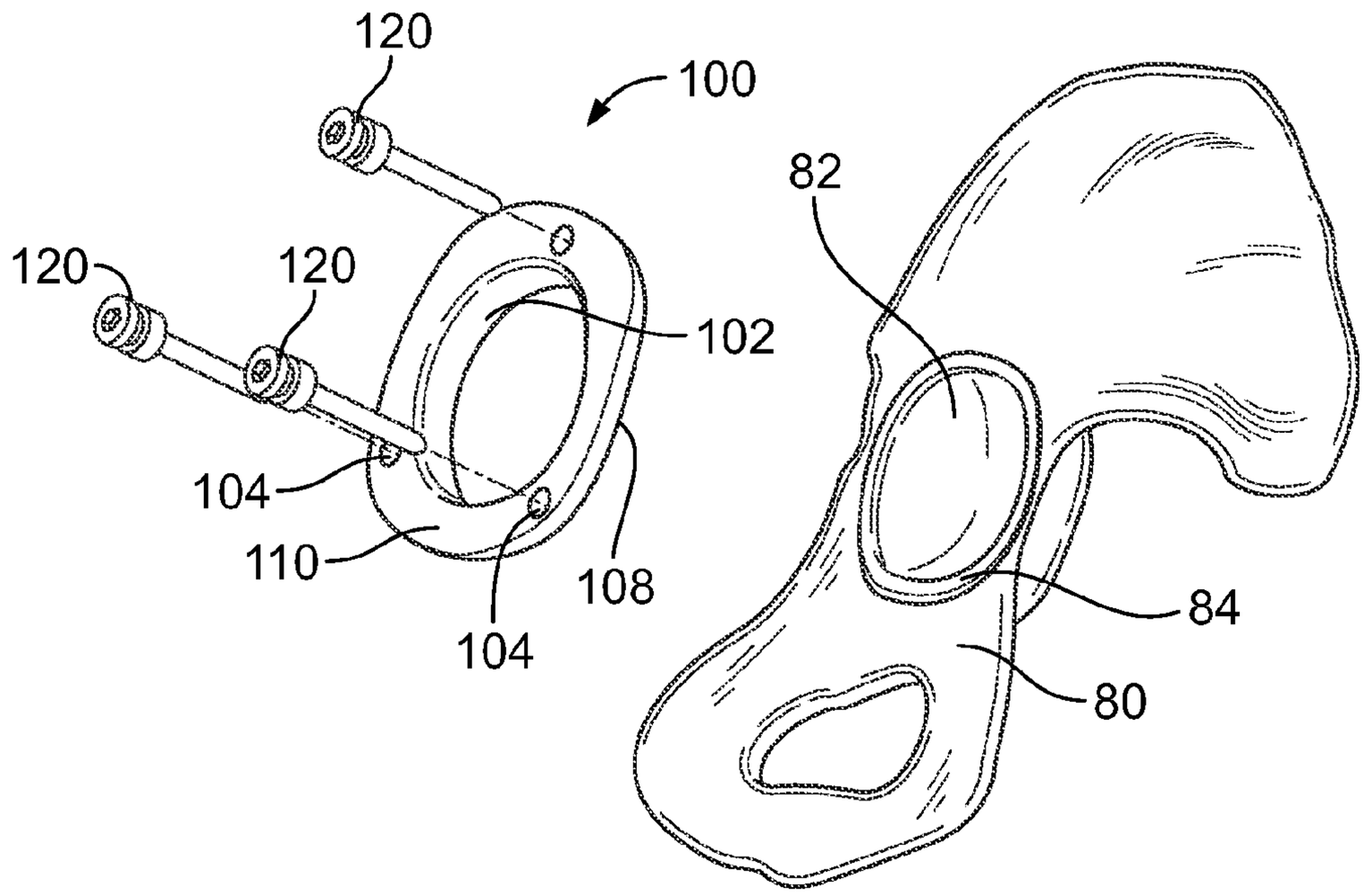
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FIG. 1A

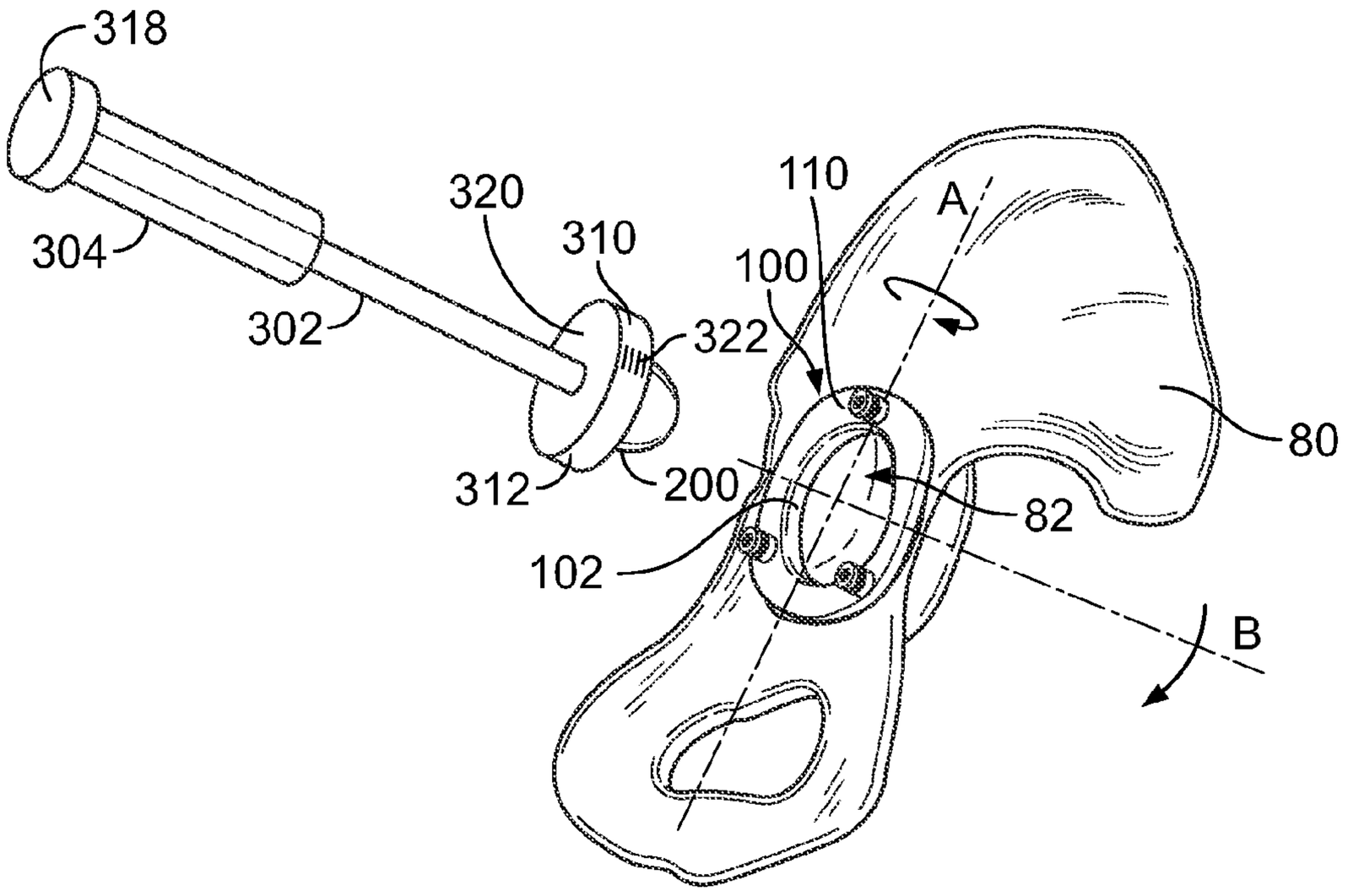
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FIG. 2

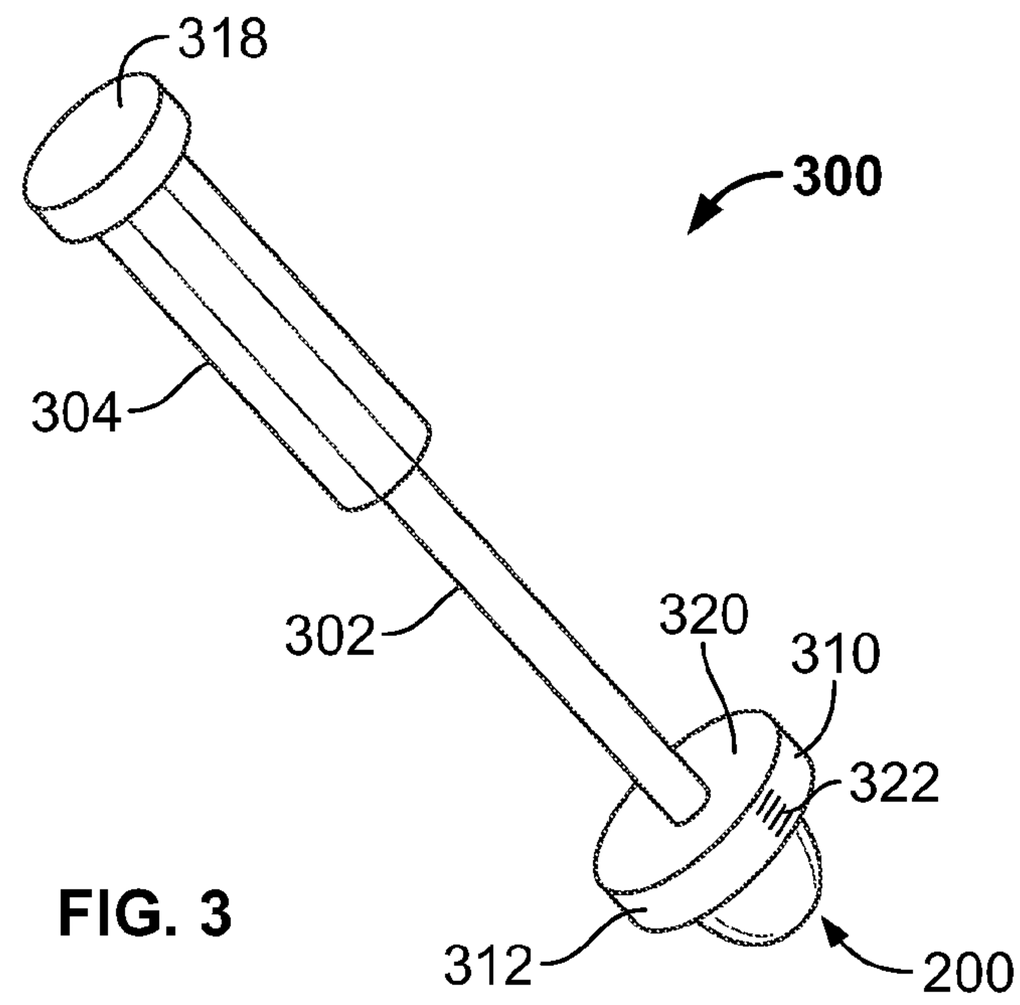

FIG. 3

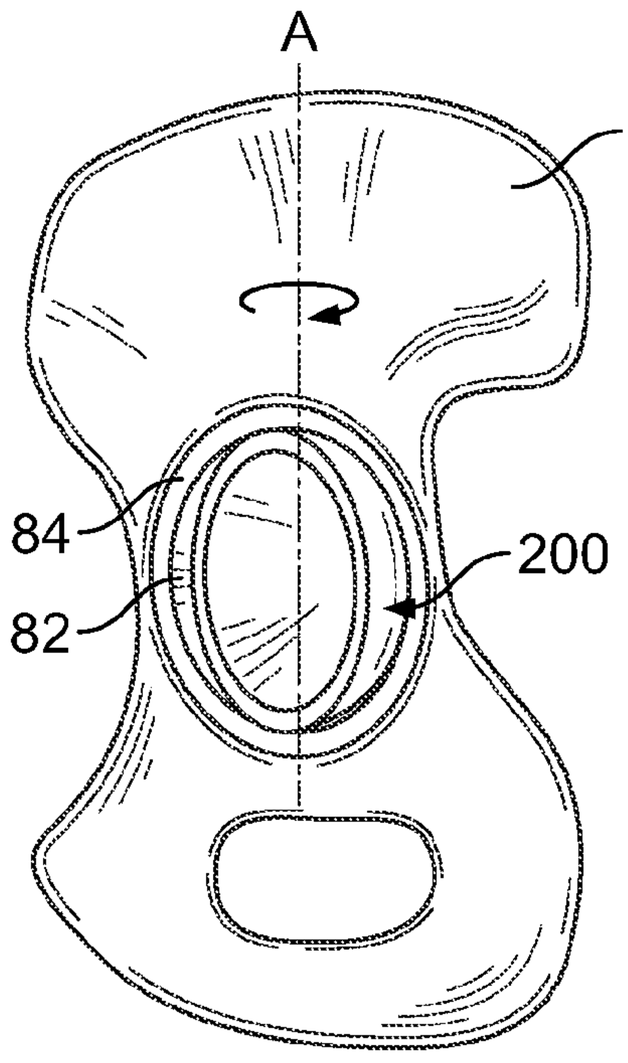

FIG. 3A

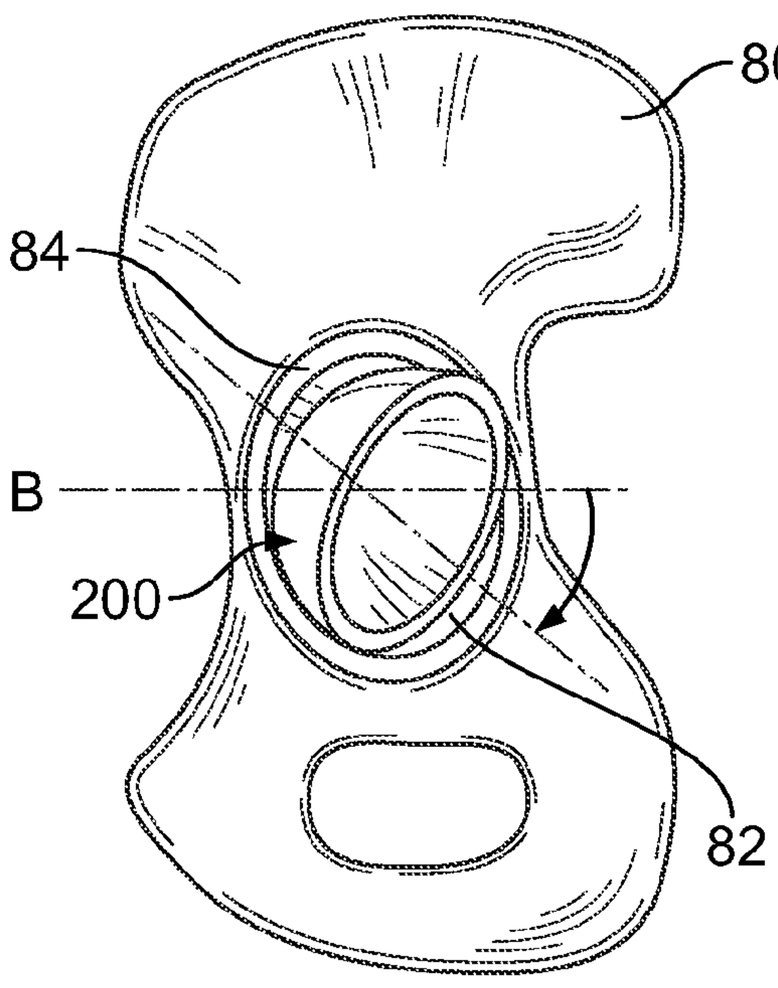

FIG. 3B

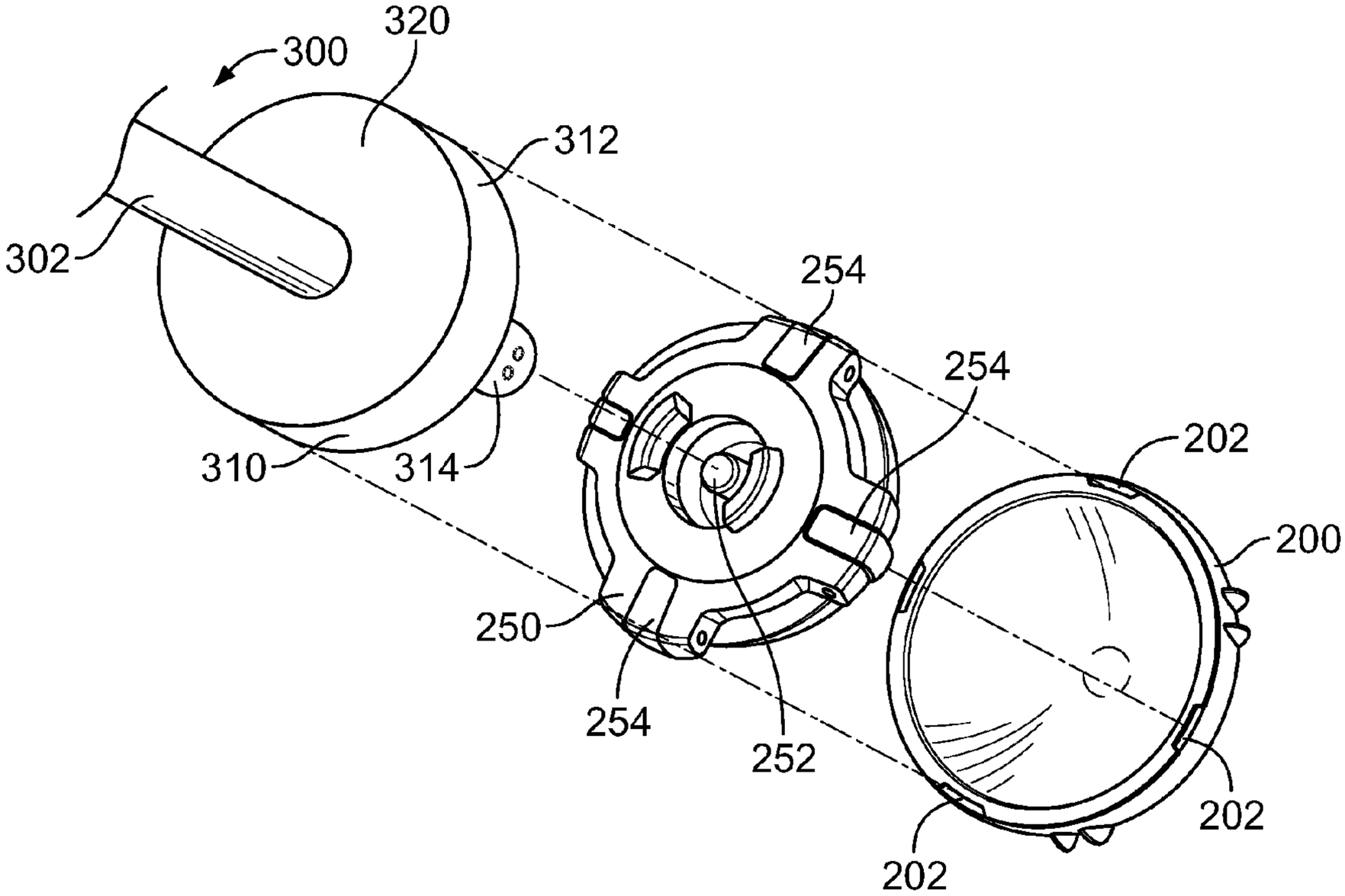

FIG. 4

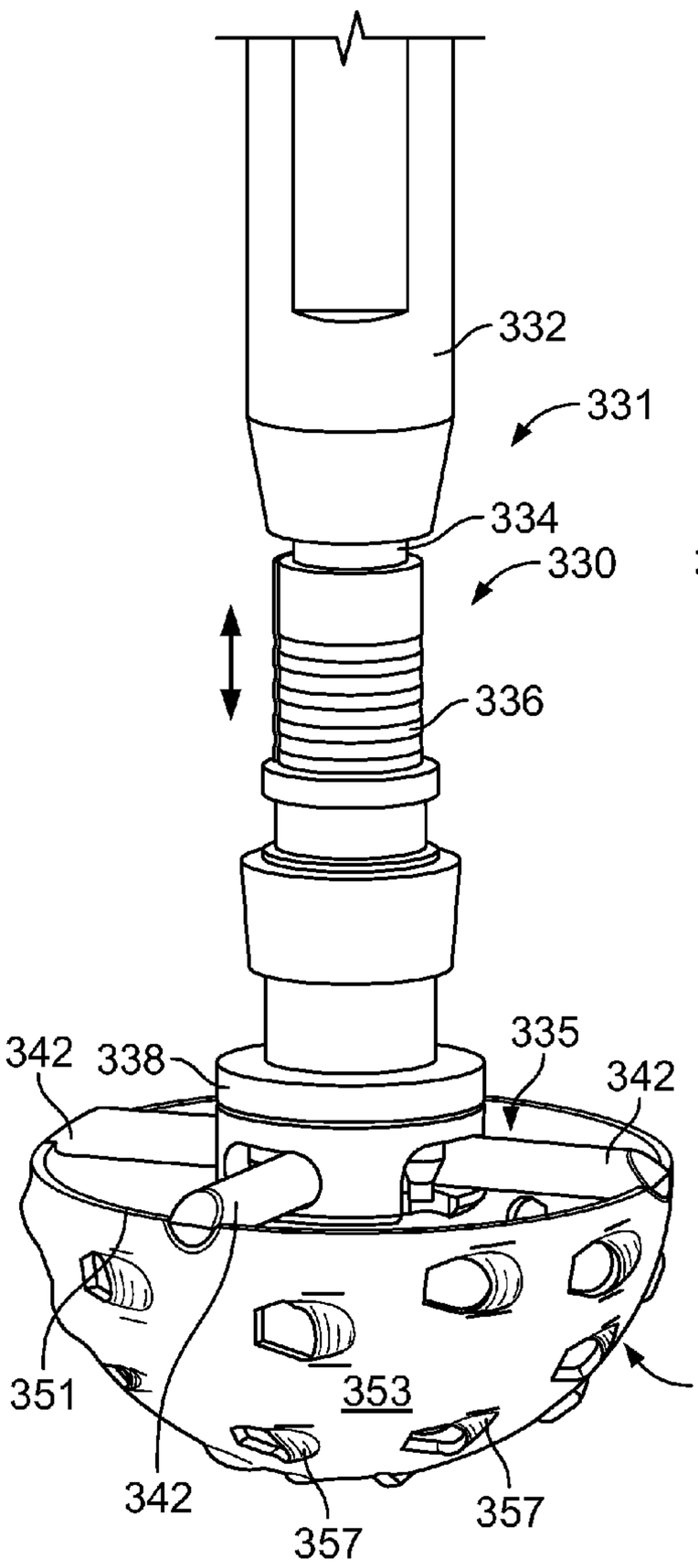
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FIG. 4A

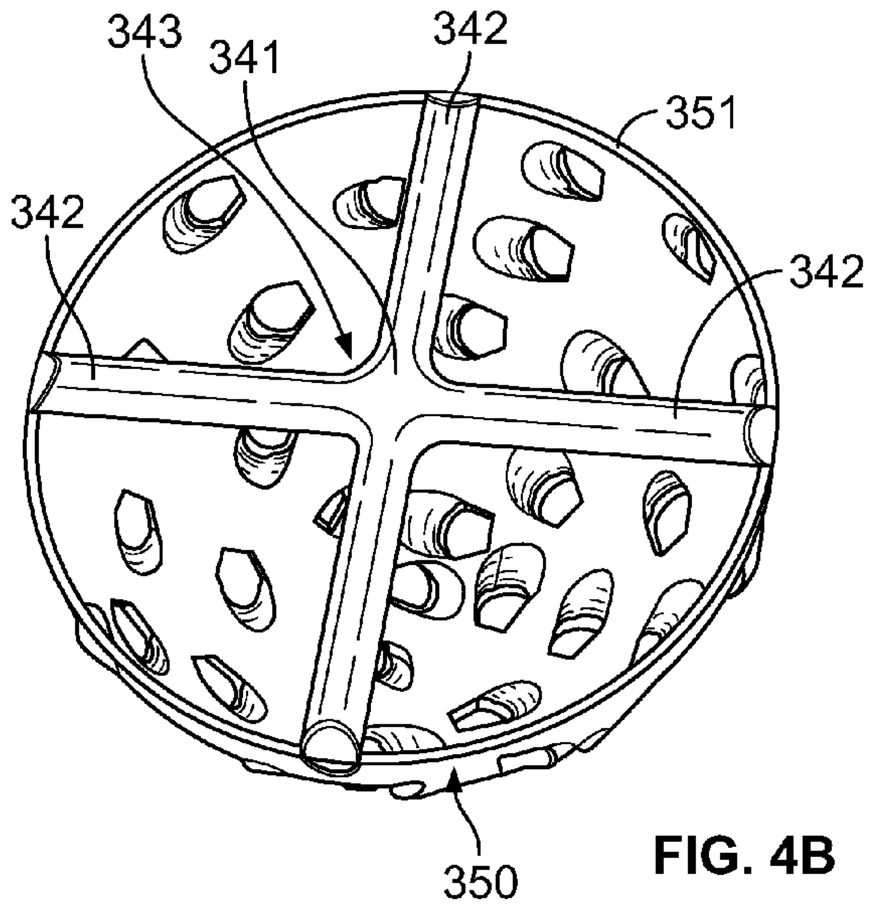
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FIG. 4B

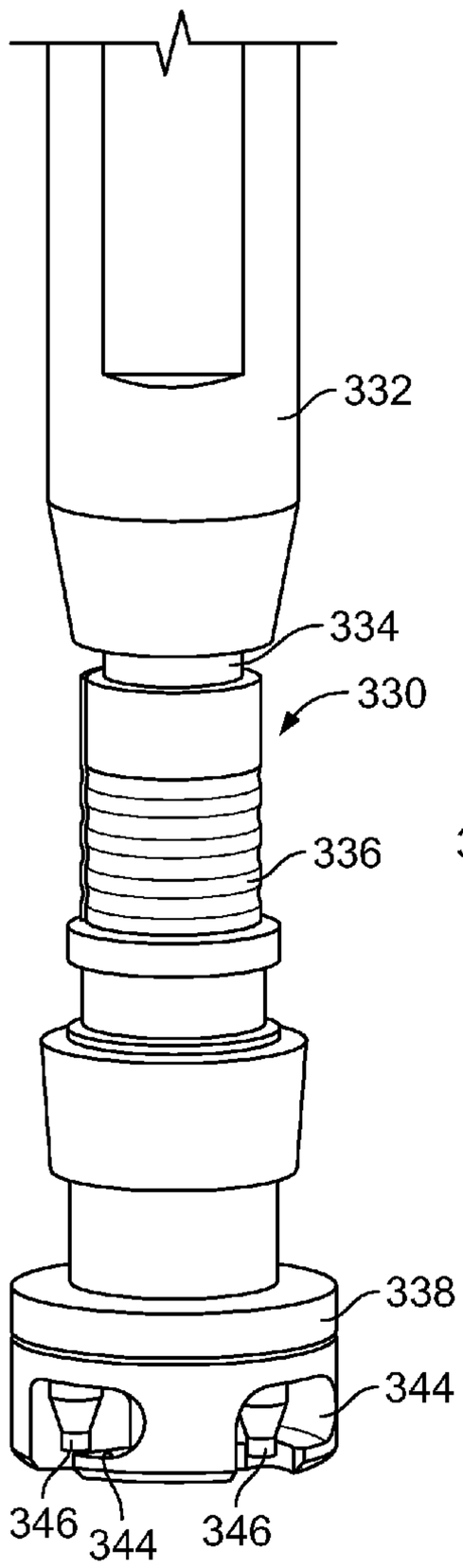
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FIG. 4C

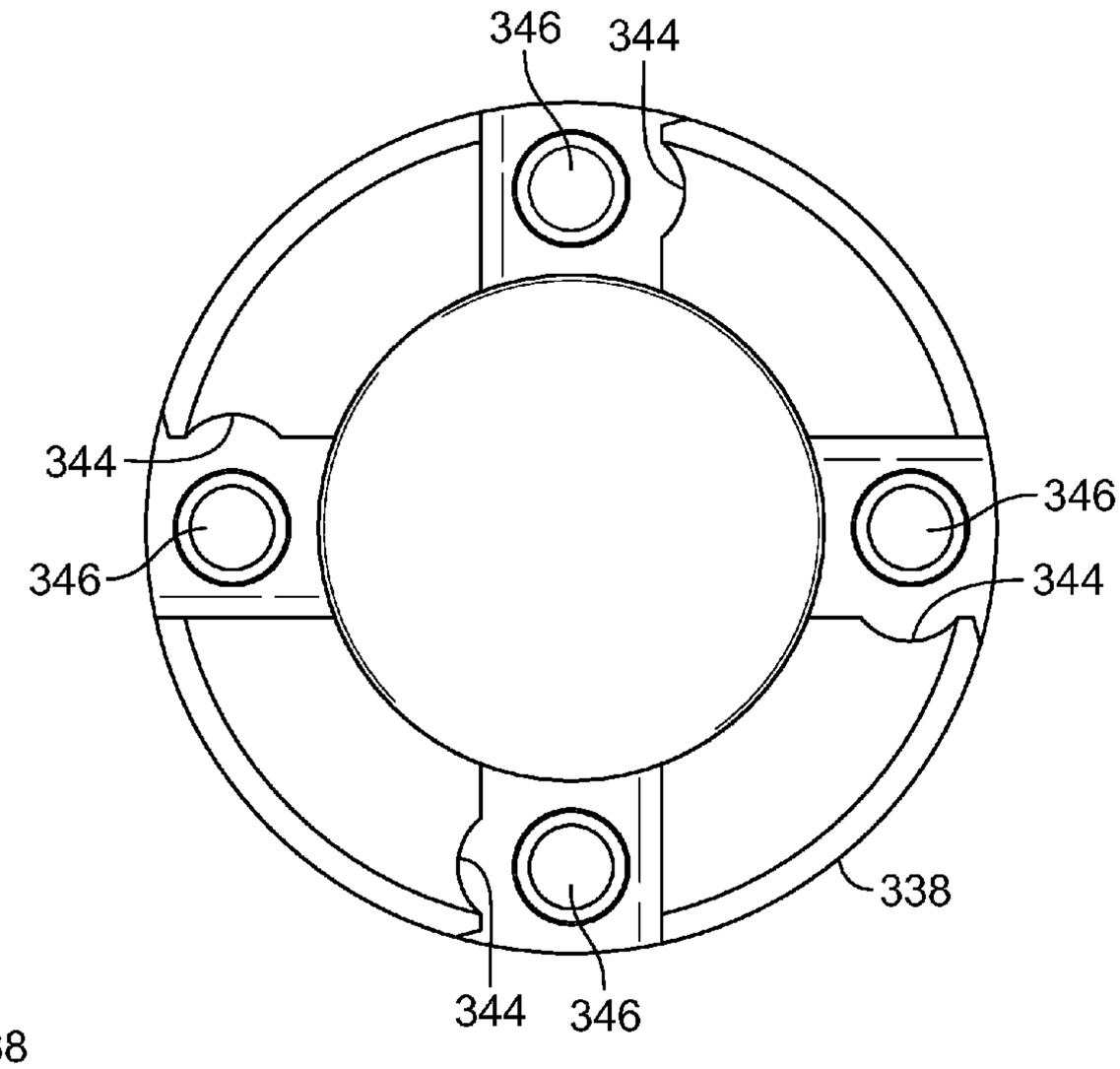
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FIG. 4D

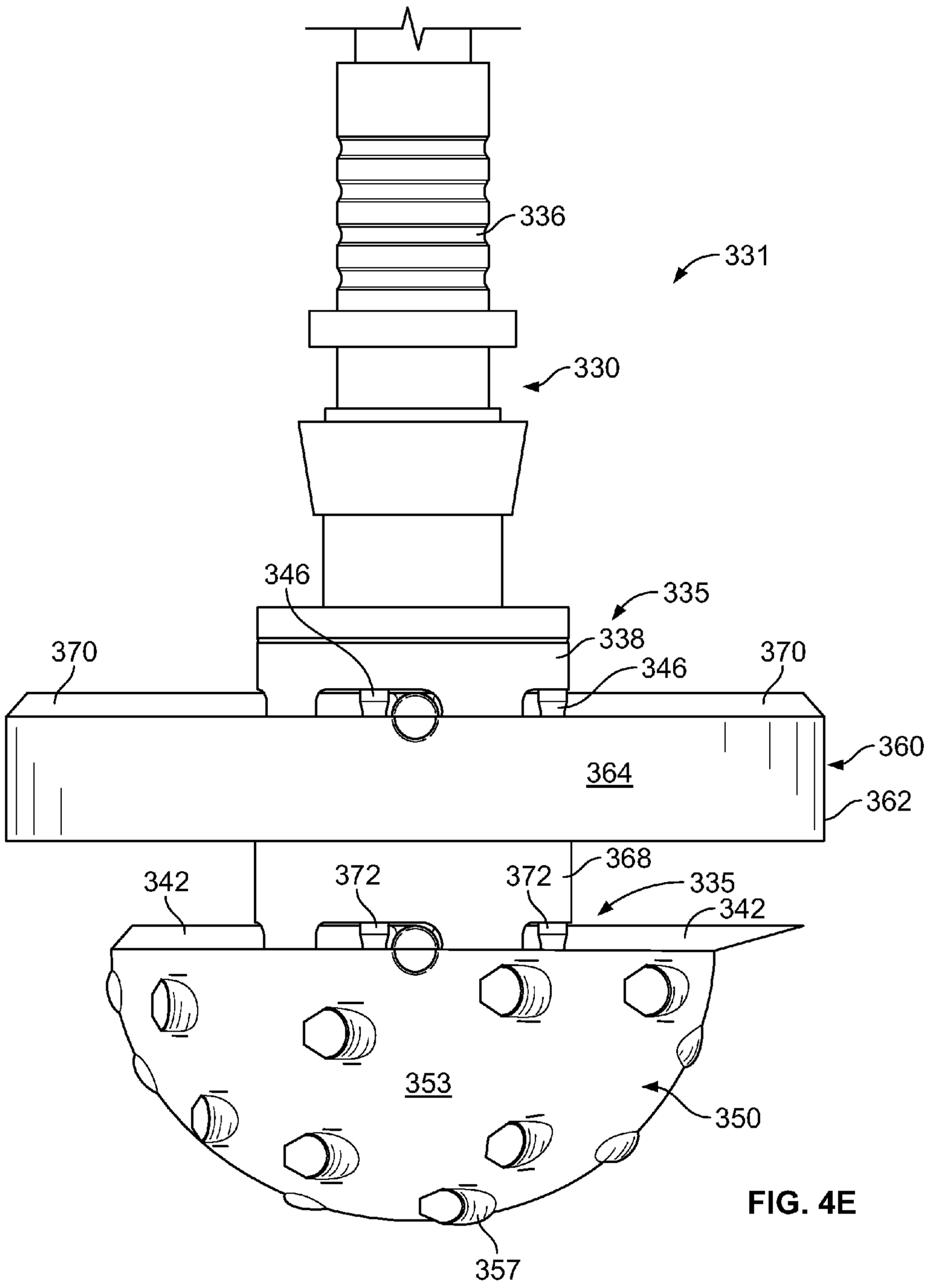
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FIG. 4E

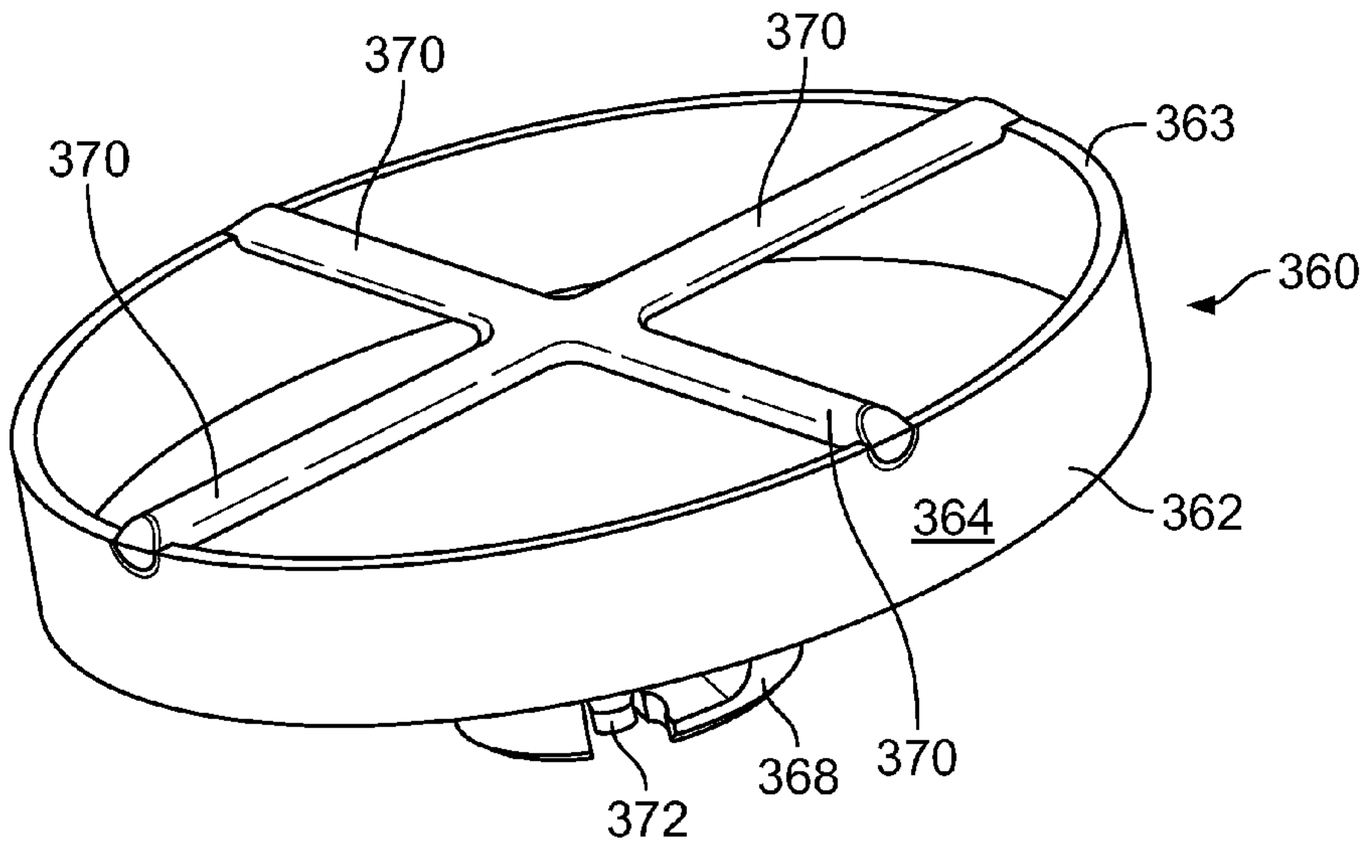
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FIG. 4F

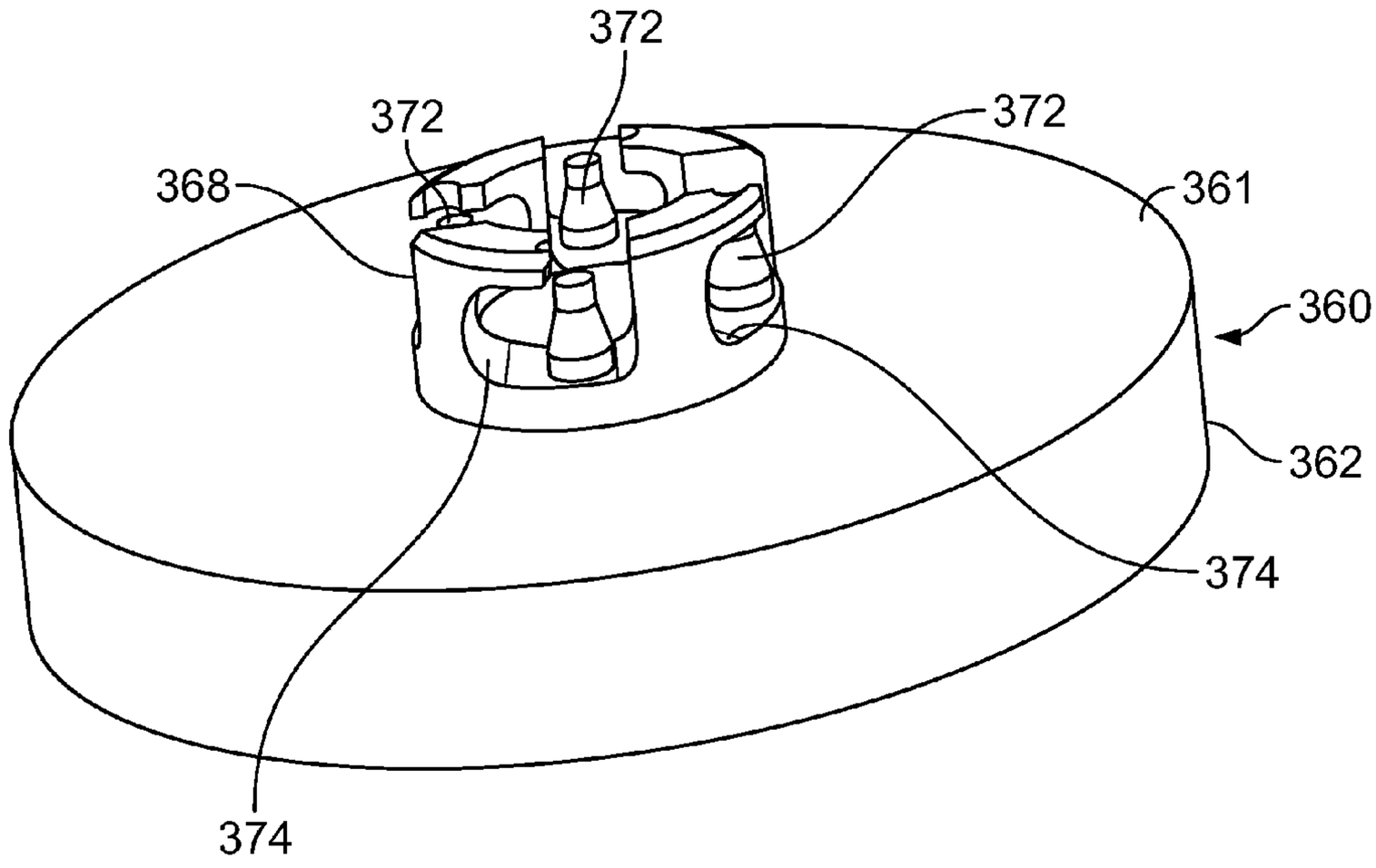
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FIG. 4G

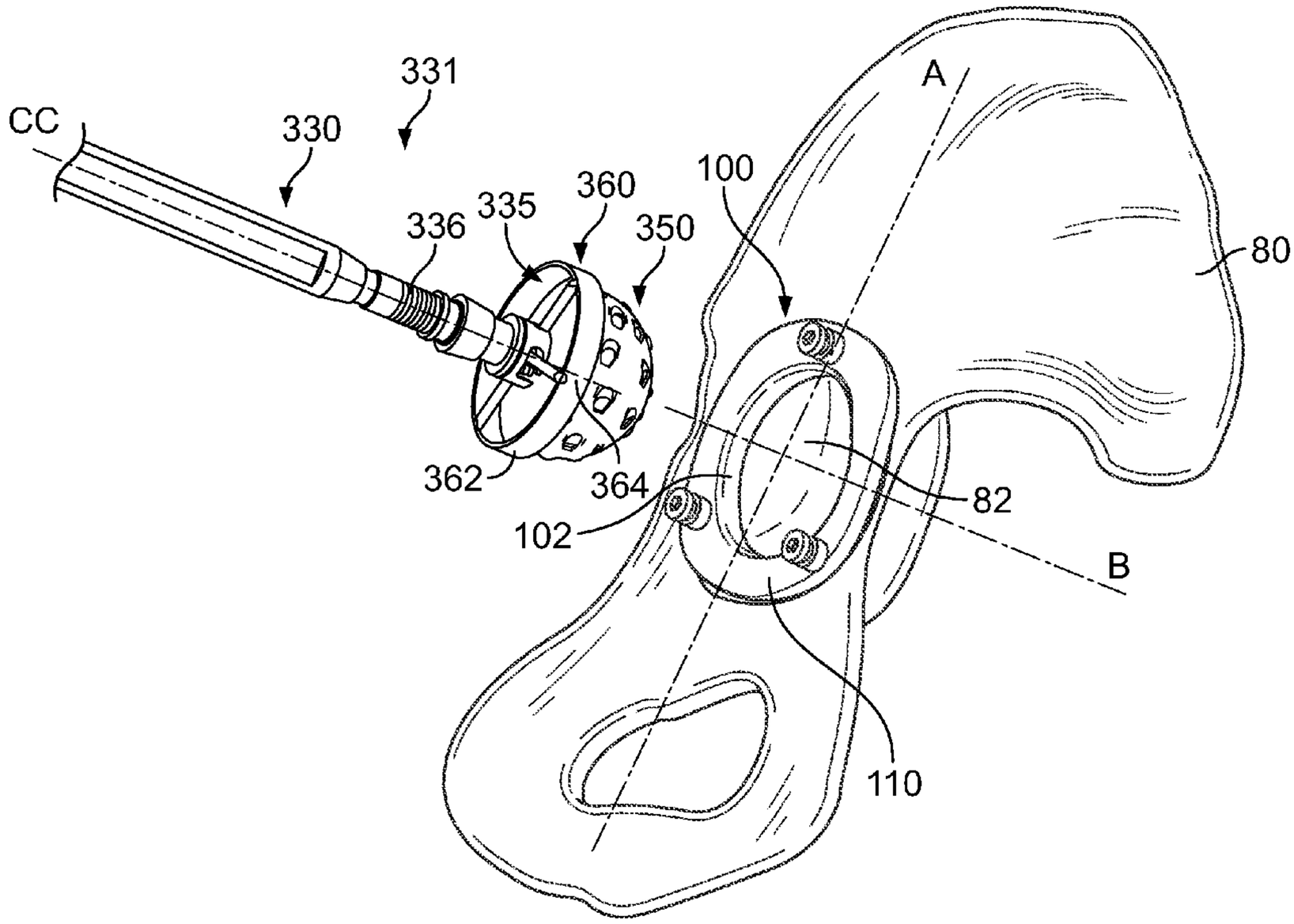

FIG. 4H

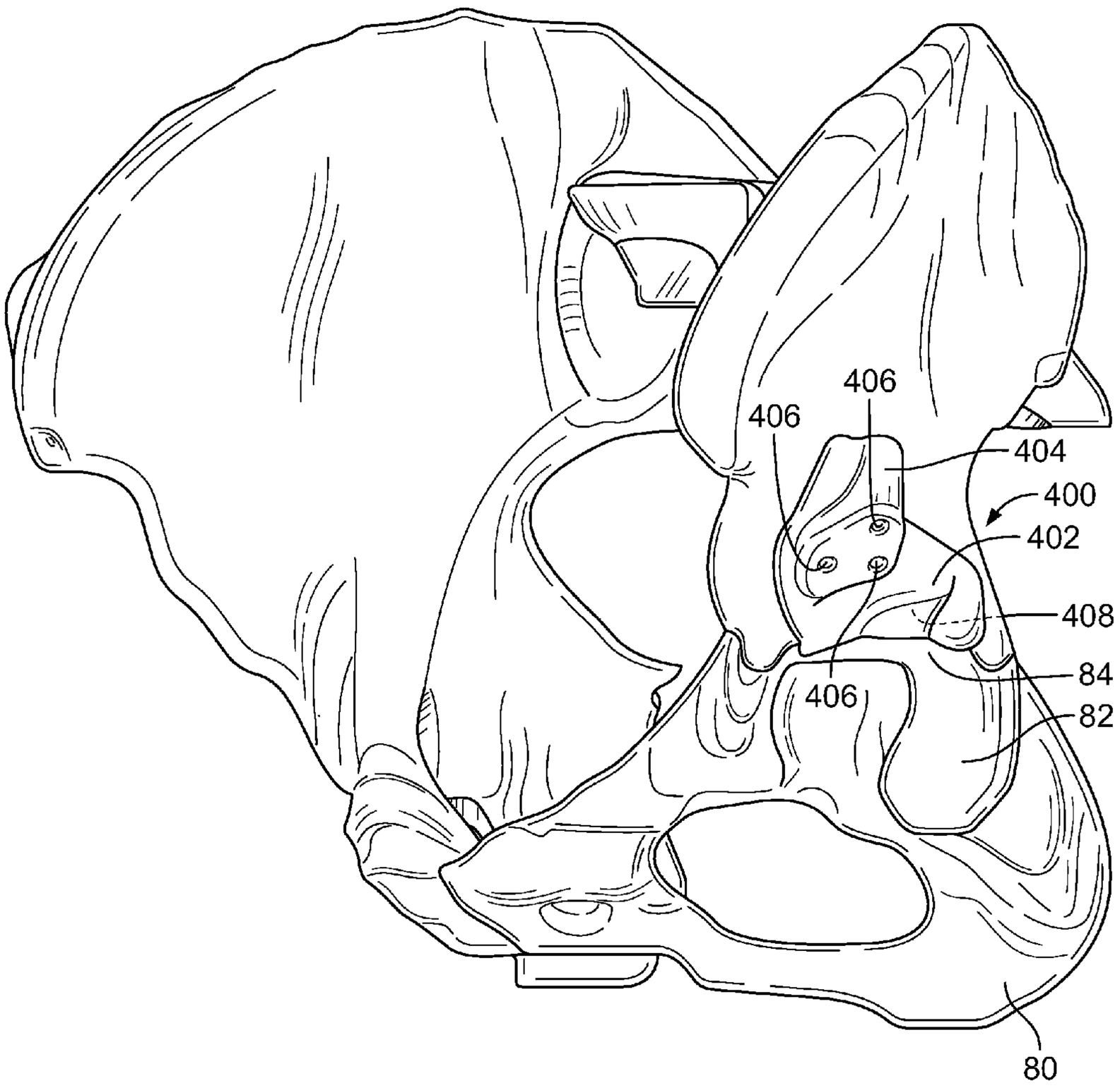

FIG. 5

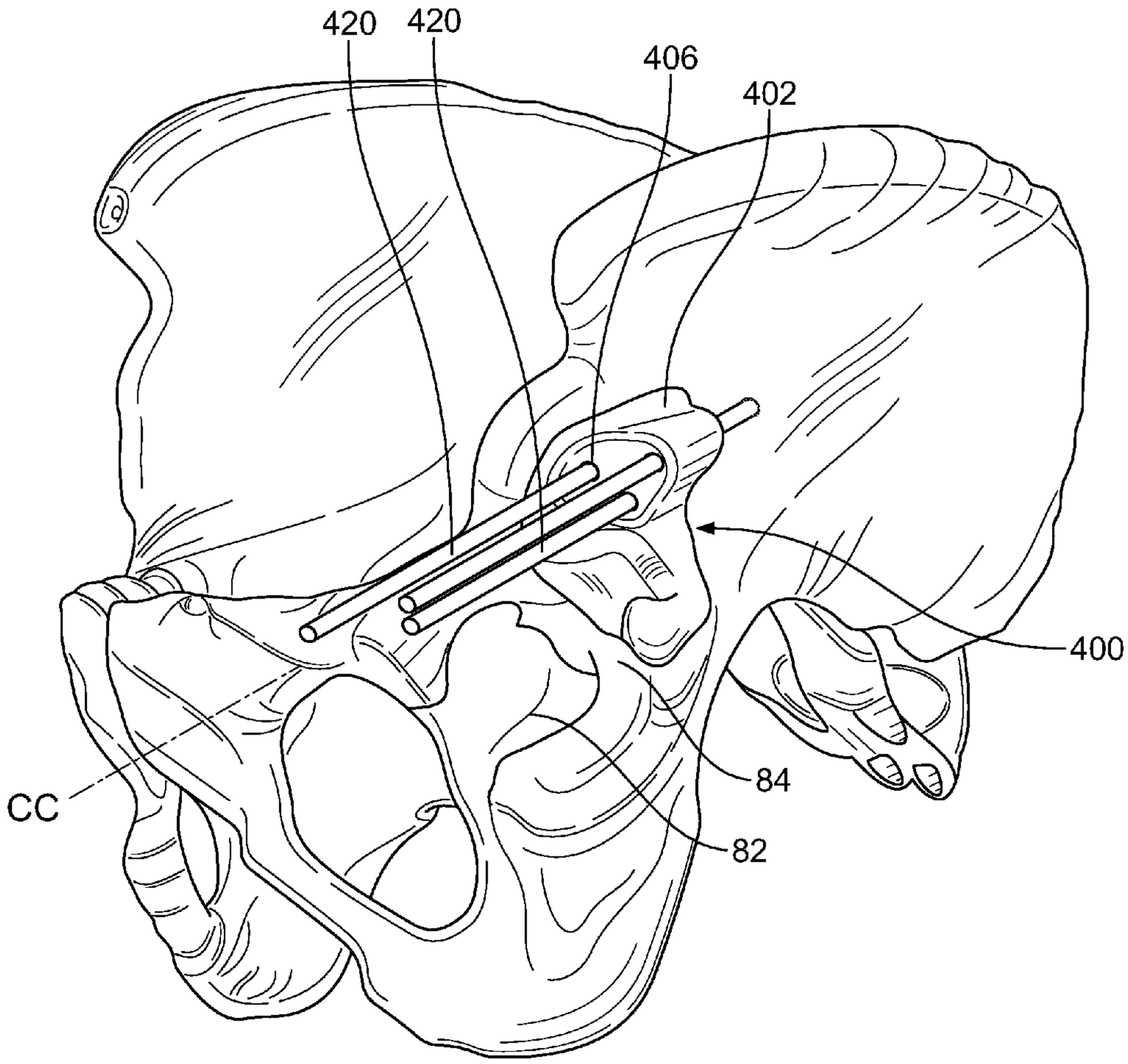

FIG. 6

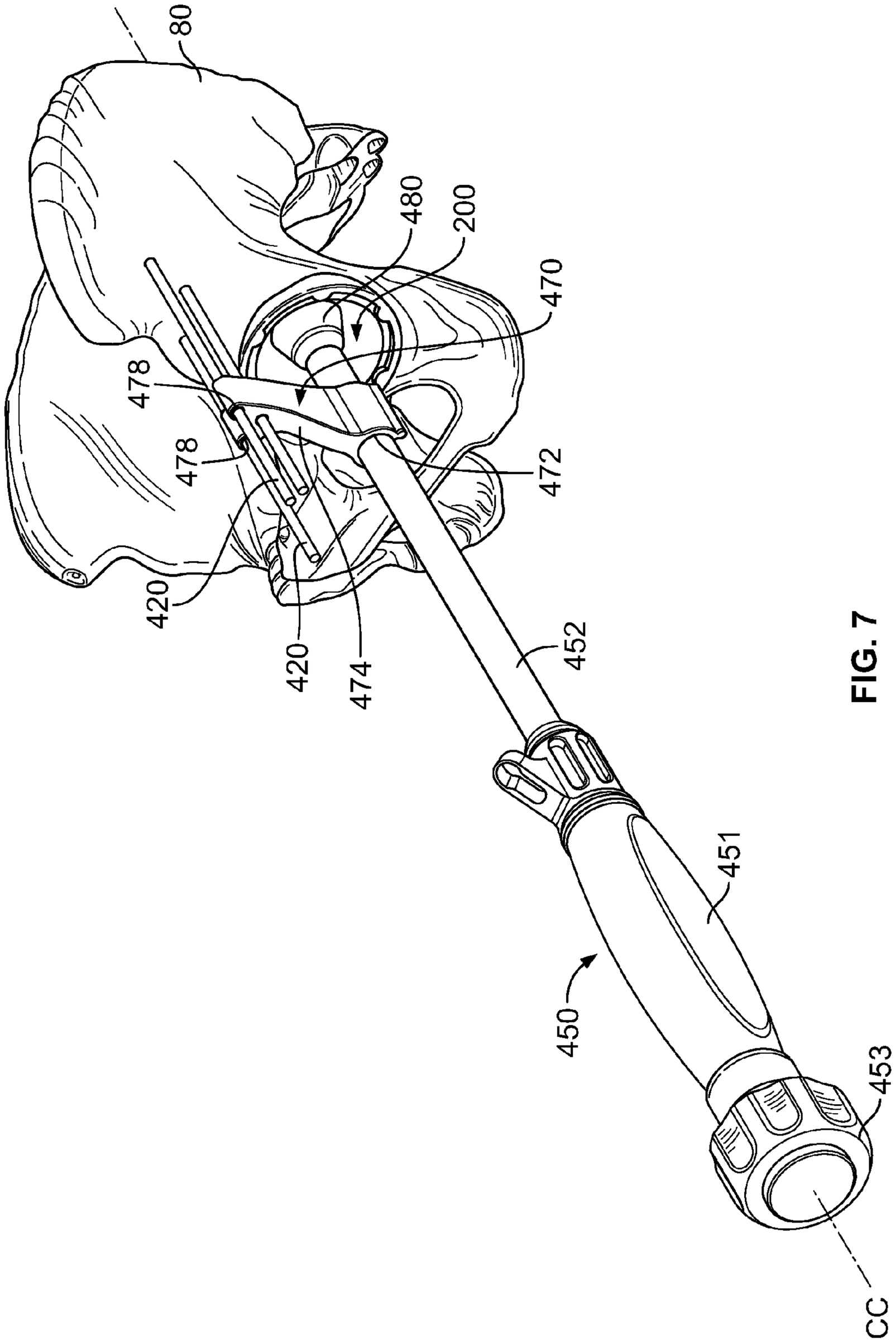

FIG. 7

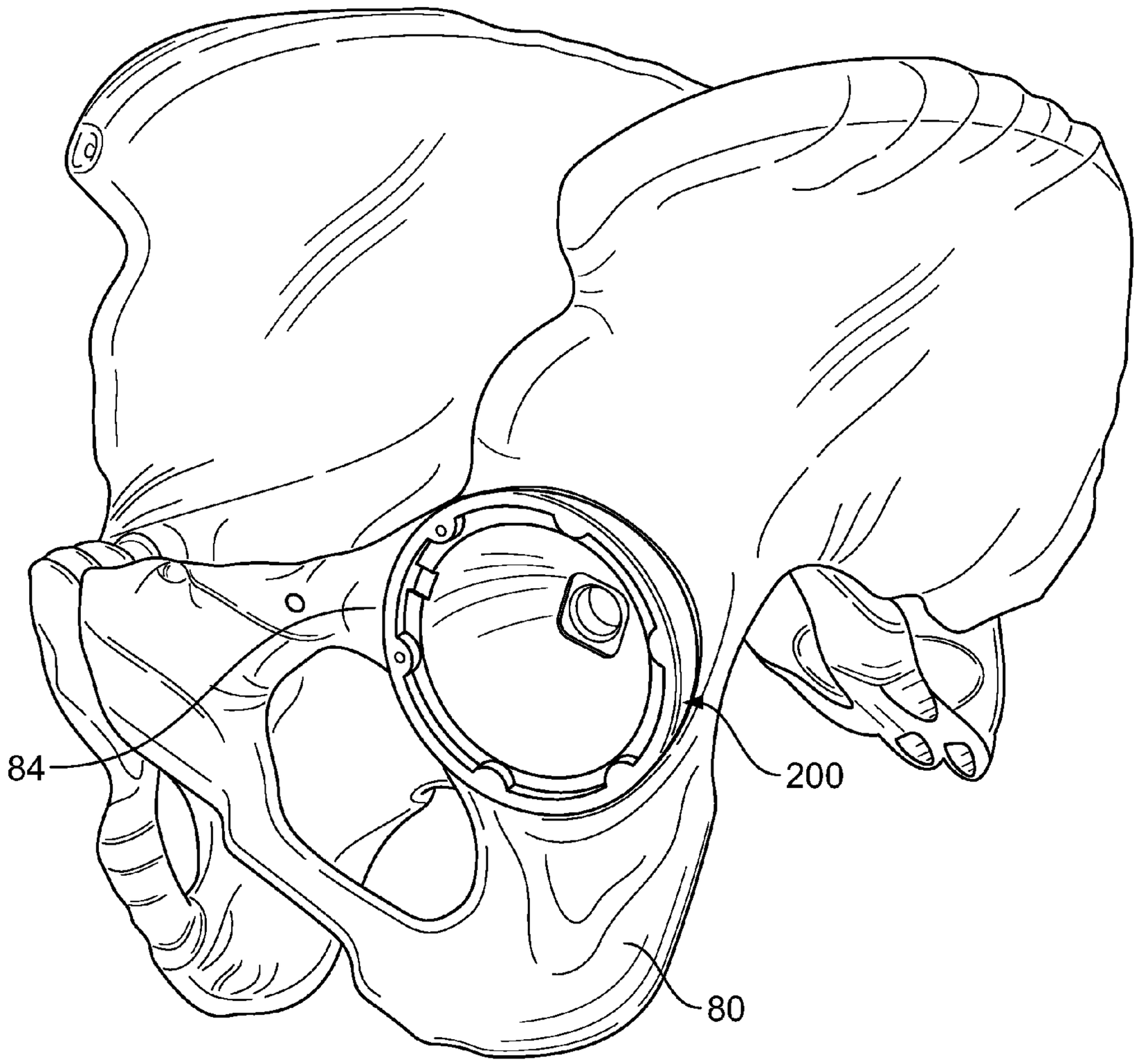

FIG. 8

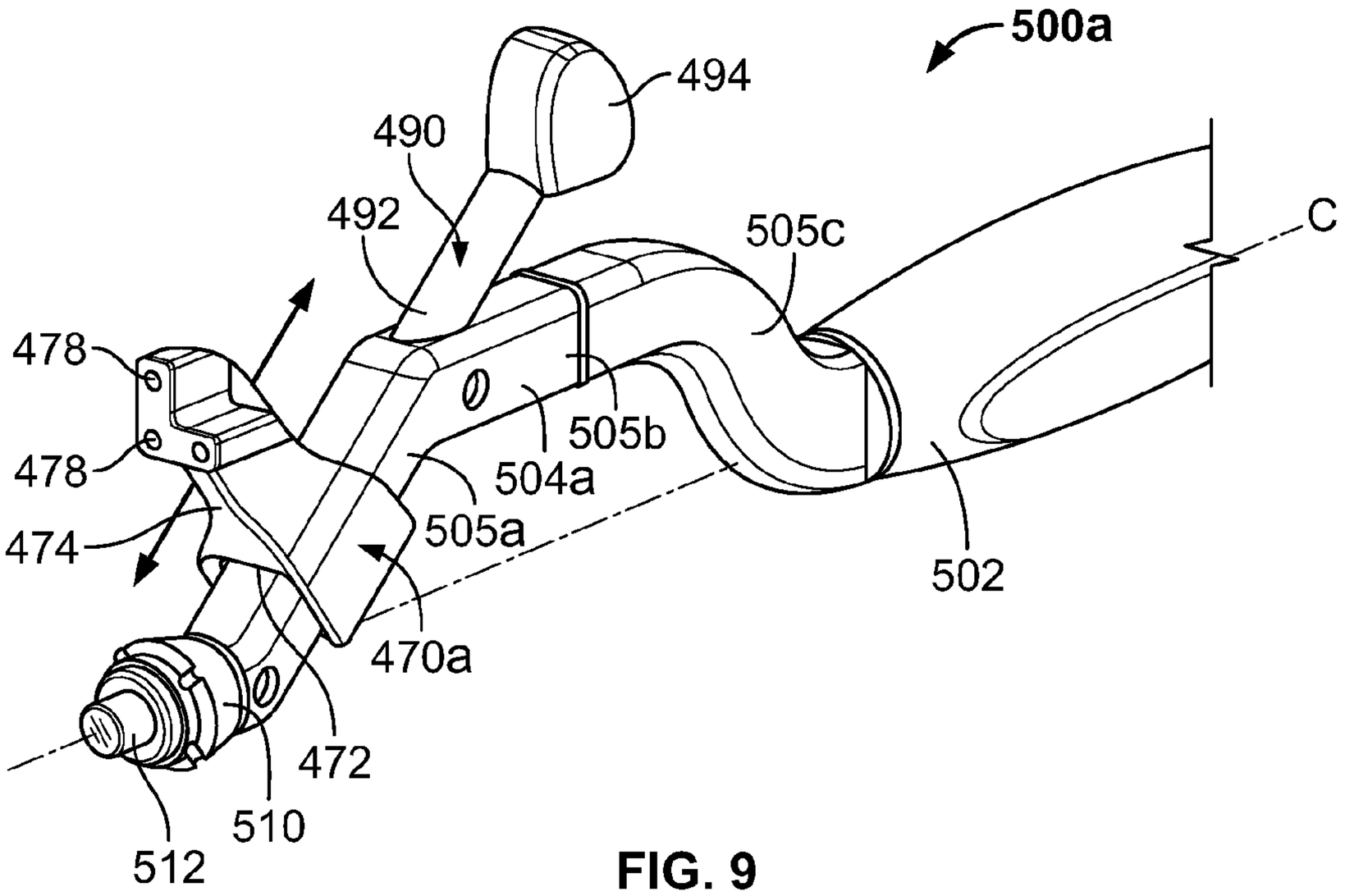
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FIG. 9

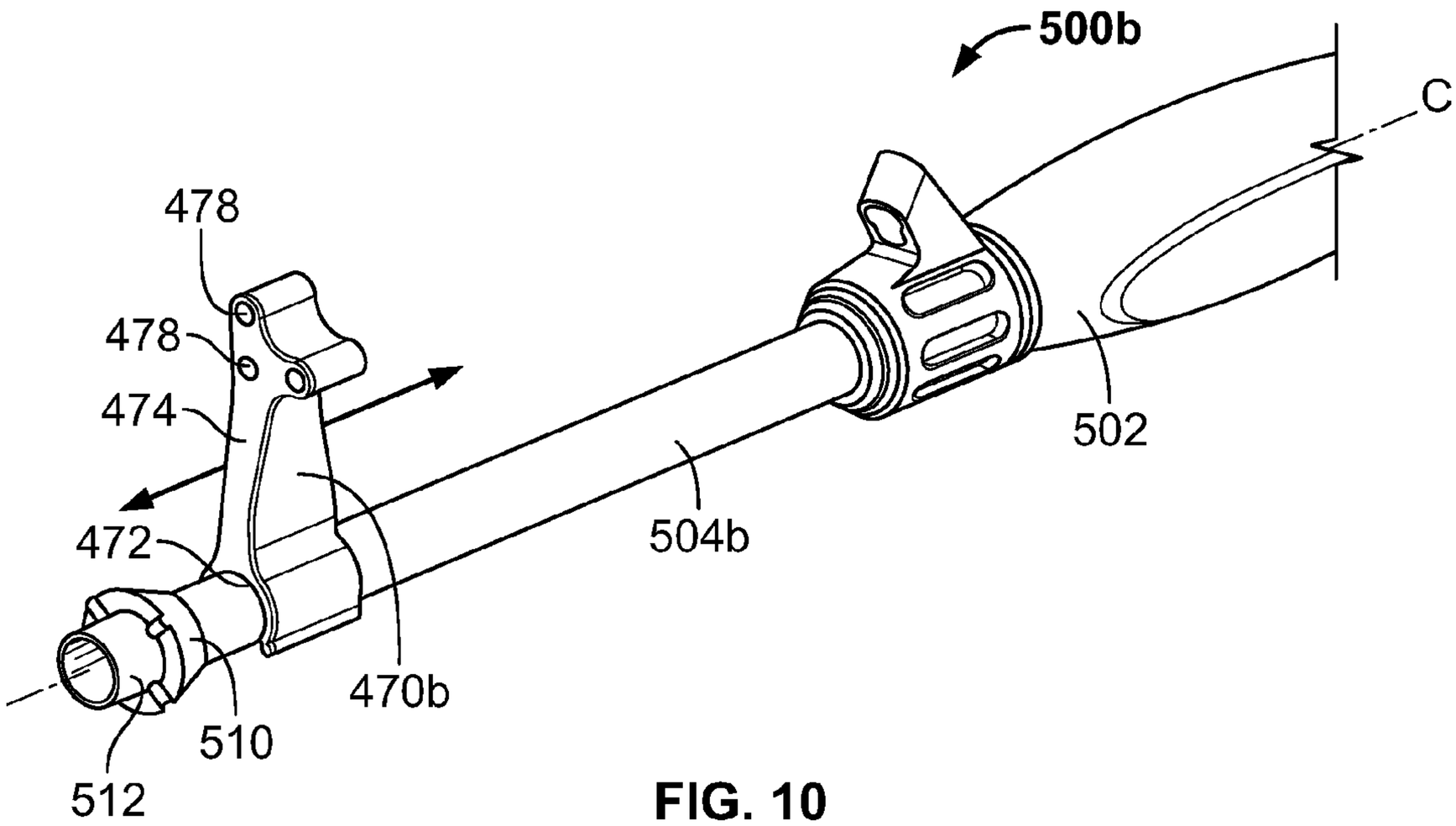
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FIG. 10

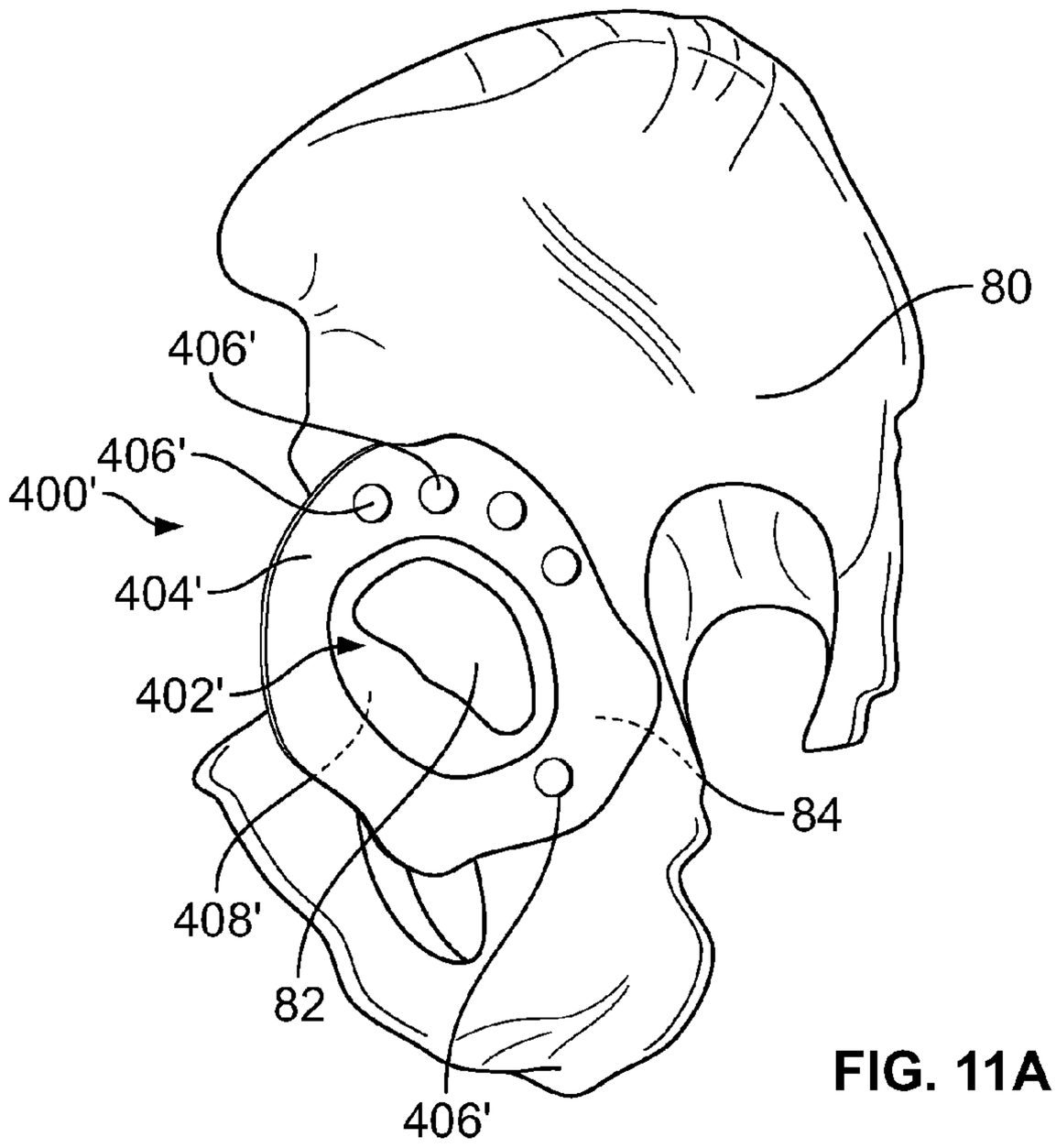

FIG. 11A

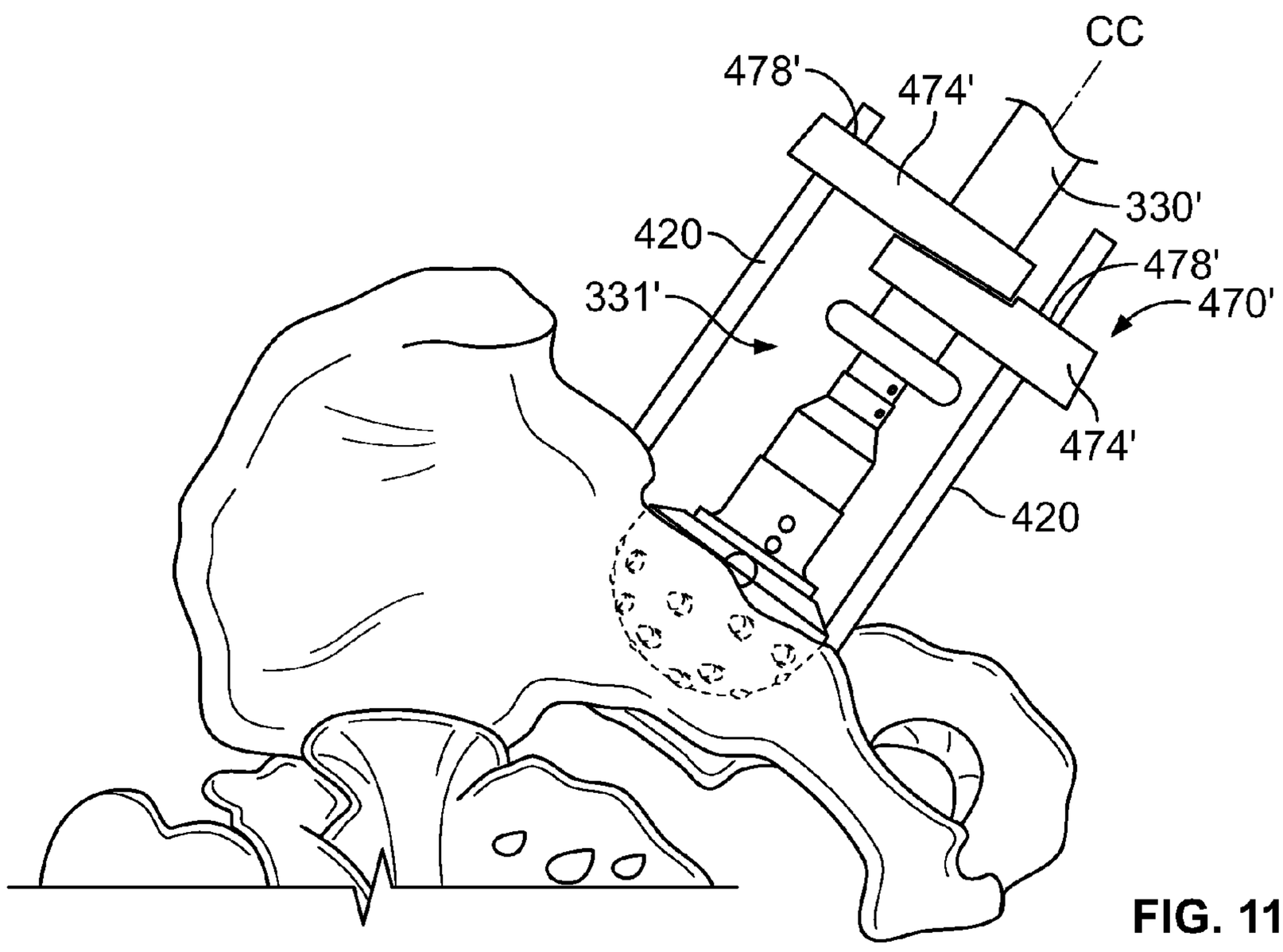

FIG. 11B

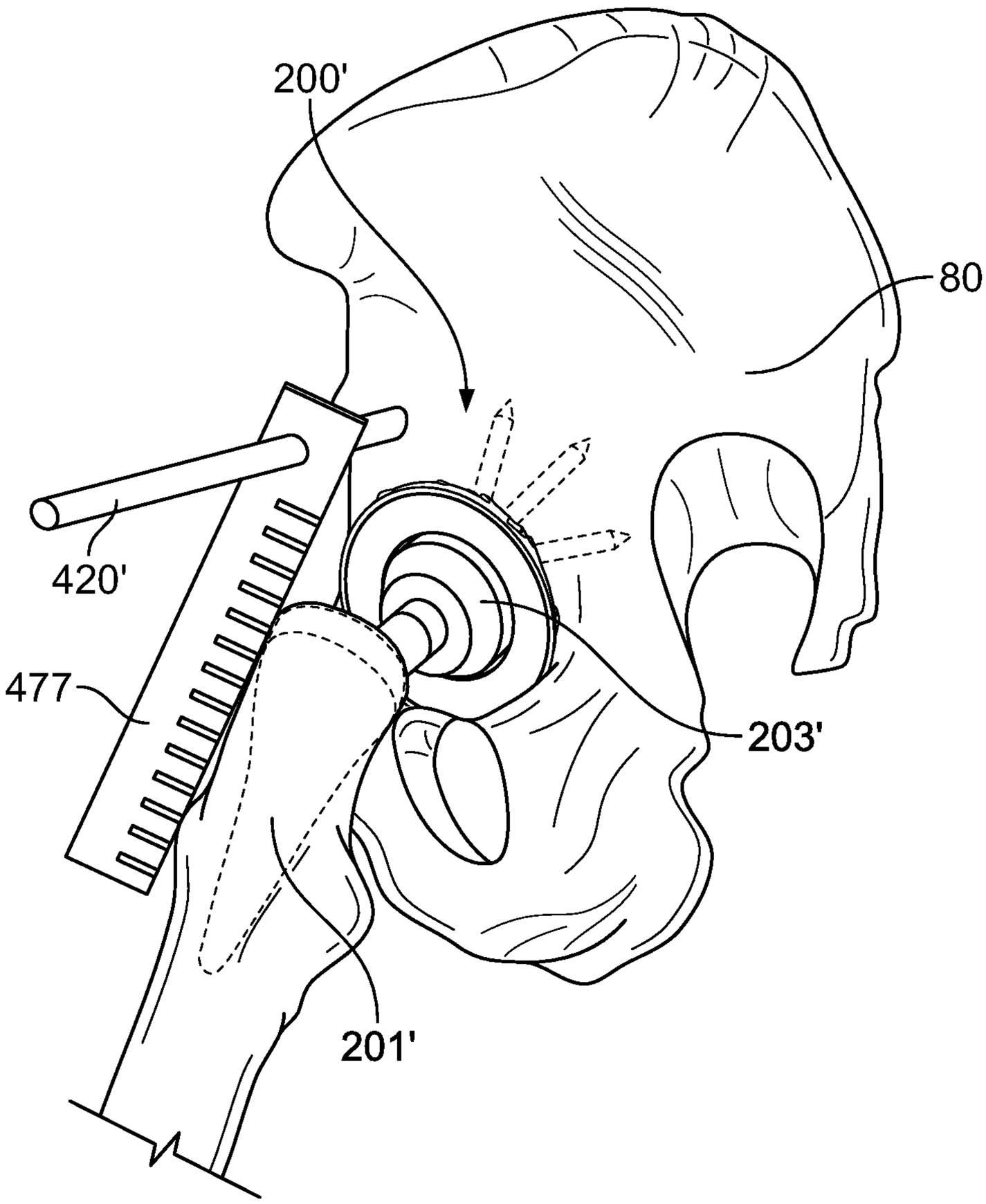

FIG. 11C

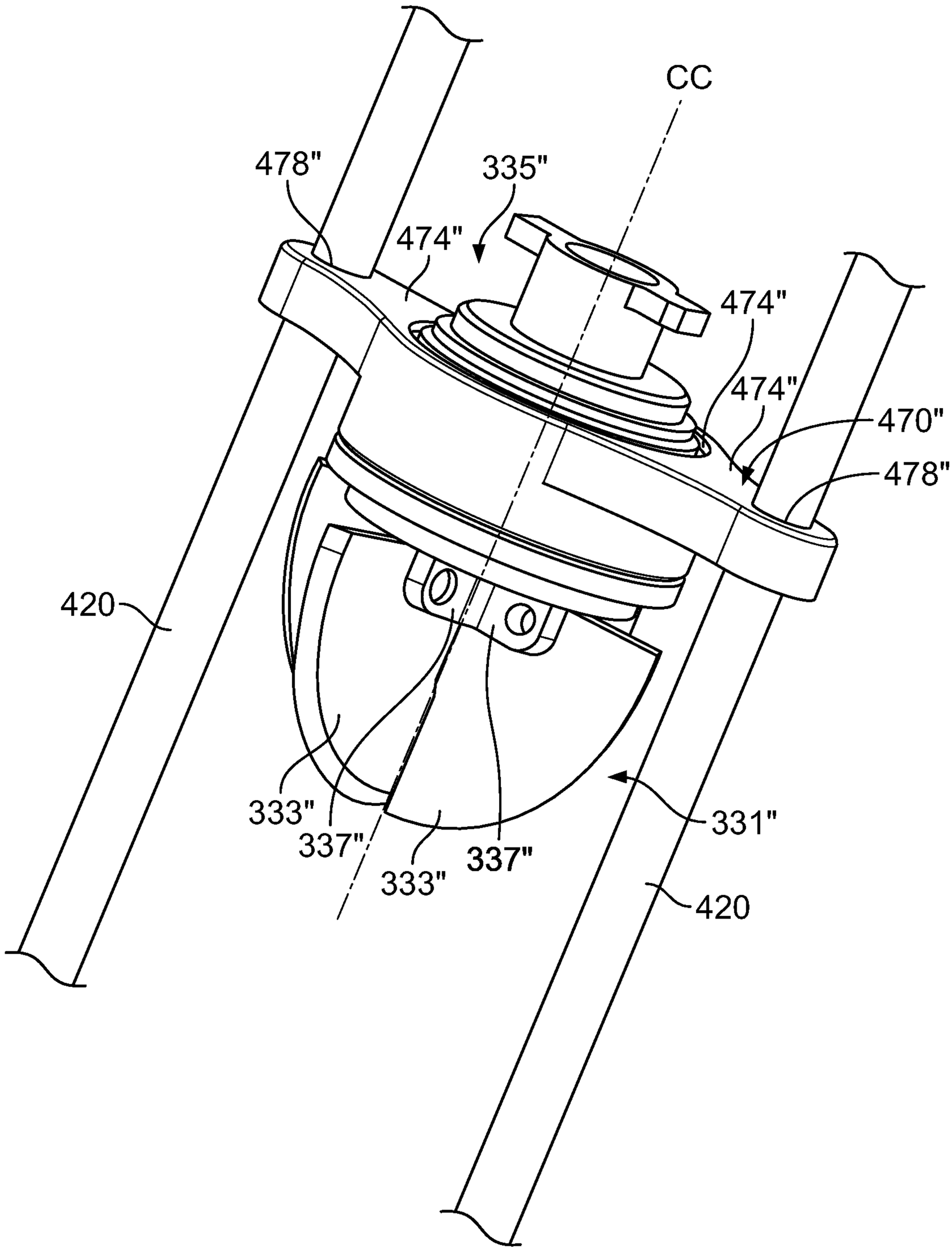

FIG. 12

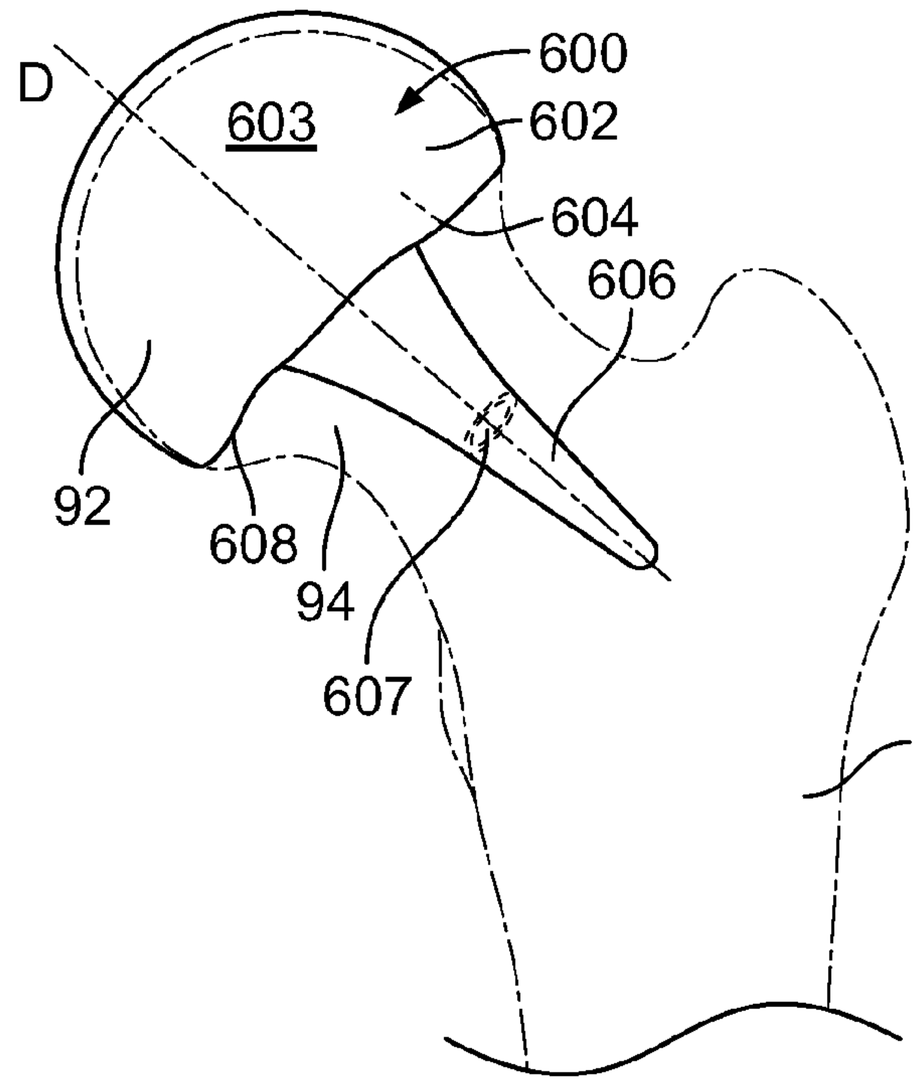

FIG. 13

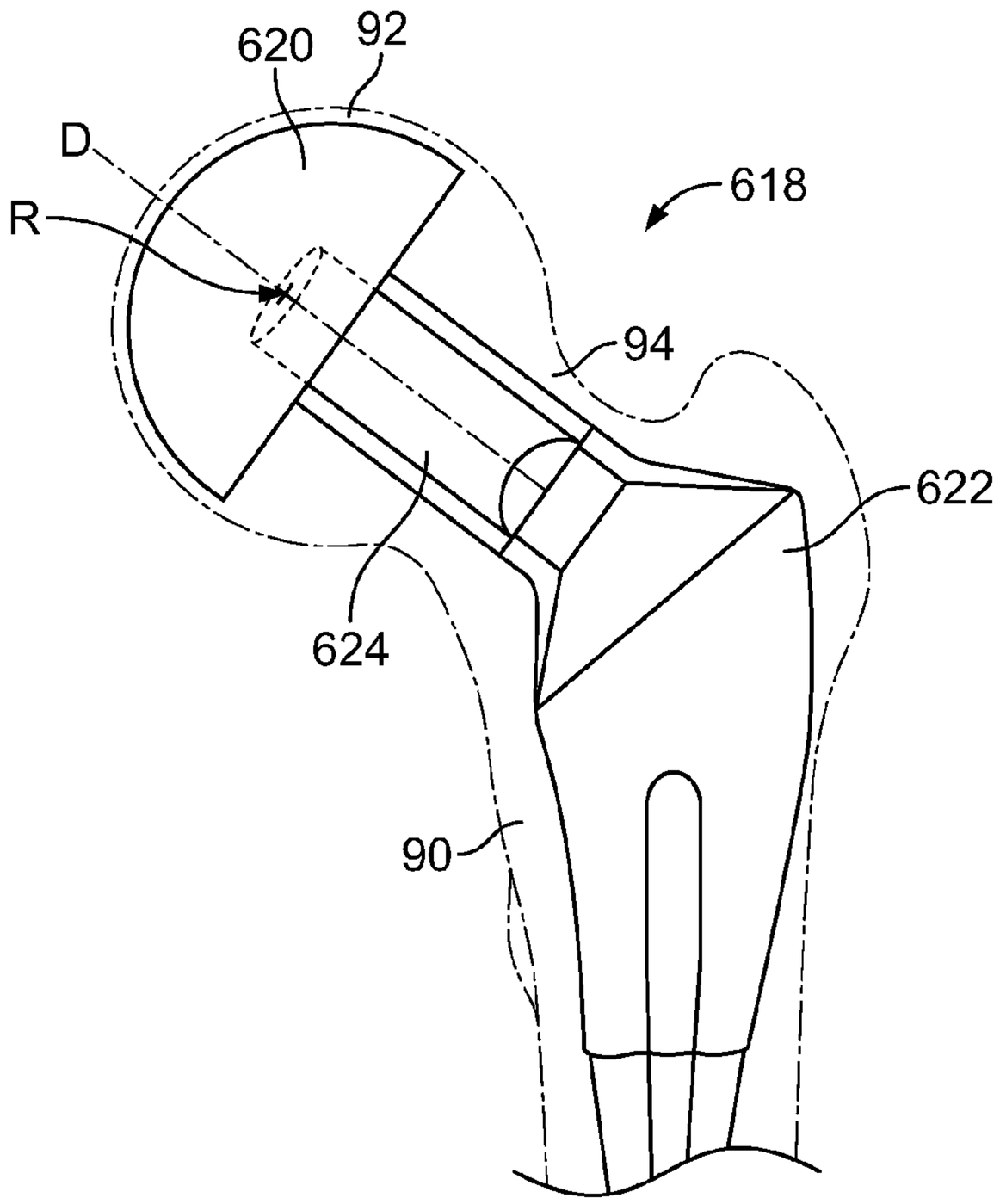

FIG. 14A

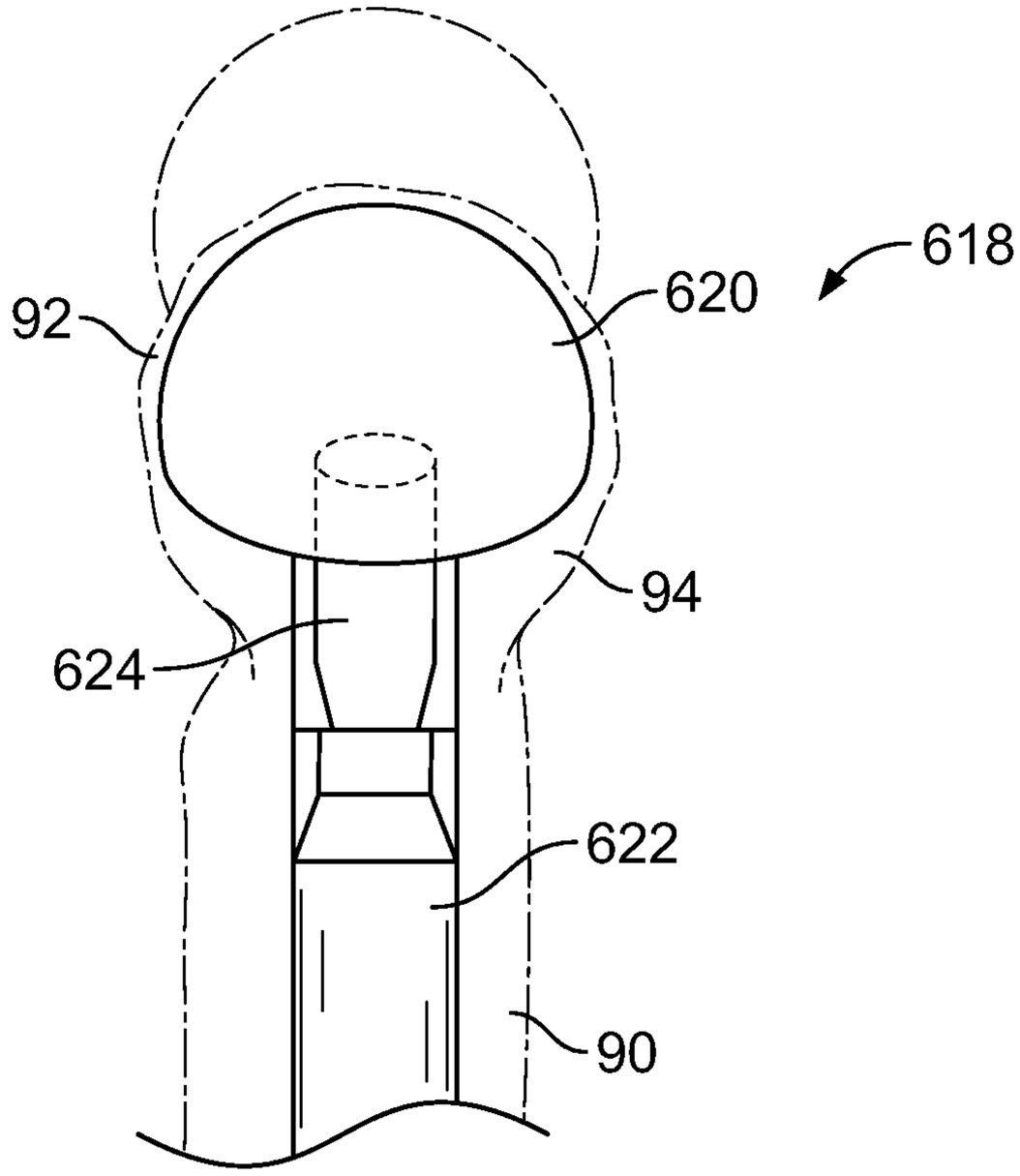

FIG. 14B

PATIENT-SPECIFIC ACETABULAR ALIGNMENT GUIDES

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Application No. 61/446,660, filed on Feb. 25, 2011.

This application is a continuation-in-part of U.S. application Ser. Nos. 13/041,469, 13/041,495, 13/041,665 and 13/041,883, each filed on Mar. 7, 2011, each of which is a continuation-in-part of U.S. application Ser. No. 12/978,069 filed Dec. 23, 2010, which is a continuation-in-part of U.S. application Ser. No. 12/973,214, filed Dec. 20, 2010, which is a continuation-in-part of U.S. application Ser. No. 12/955,361 filed Nov. 29, 2010, which is a continuation-in-part of U.S. application Ser. Nos. 12/938,913 and 12/938,905, both filed Nov. 3, 2010, each of which is a continuation-in-part of U.S. application Ser. No. 12/893,306, filed Sep. 29, 2010, which is a continuation-in-part of U.S. application Ser. No. 12/888,005, filed Sep. 22, 2010, which is a continuation-in-part of U.S. application Ser. No. 12/714,023, filed Feb. 26, 2010, which is a continuation-in-part of U.S. application Ser. No. 12/571,969, filed Oct. 1, 2009, which is a continuation-in-part of U.S. application Ser. No. 12/486,992, filed Jun. 18, 2009, and is a continuation-in-part of U.S. application Ser. No. 12/389,901, filed Feb. 20, 2009, which is a continuation-in-part of U.S. application Ser. No. 12/211,407, filed Sep. 16, 2008, which is a continuation-in-part of U.S. application Ser. No. 12/039,849, filed Feb. 29, 2008, which: (1) claims the benefit of U.S. Provisional Application No. 60/953,620, filed on Aug. 2, 2007, U.S. Provisional Application No. 60/947,813, filed on Jul. 3, 2007, U.S. Provisional Application No. 60/911,297, filed on Apr. 12, 2007, and U.S. Provisional Application No. 60/892,349, filed on Mar. 1, 2007; (2) is a continuation-in-part U.S. application Ser. No. 11/756,057, filed on May 31, 2007, which claims the benefit of U.S. Provisional Application No. 60/812,694, filed on Jun. 9, 2006; (3) is a continuation-in-part of U.S. application Ser. No. 11/971,390, filed on Jan. 9, 2008, which is a continuation-in-part of U.S. application Ser. No. 11/363,548, filed on Feb. 27, 2006, now U.S. Pat. No. 7,780,672, issued on Aug. 24, 2010; and (4) is a continuation-in-part of U.S. application Ser. No. 12/025,414, filed on Feb. 4, 2008, which claims the benefit of U.S. Provisional Application No. 60/953,637, filed on Aug. 2, 2007.

This application is continuation-in-part of U.S. application Ser. No. 12/872,663, filed on Aug. 31, 2010, which claims the benefit of U.S. Provisional Application No. 61/310,752 filed on Mar. 5, 2010.

This application is a continuation-in-part of U.S. application Ser. No. 12/483,807, filed on Jun. 12, 2009, which is a continuation-in-part of U.S. application Ser. No. 12/371,096, filed on Feb. 13, 2009, which is a continuation-in-part of U.S. application Ser. No. 12/103,824, filed on Apr. 16, 2008, which claims the benefit of U.S. Provisional Application No. 60/912,178, filed on Apr. 17, 2007.

This application is also a continuation-in-part of U.S. application Ser. No. 12/103,834, filed on Apr. 16, 2008, which claims the benefit of U.S. Provisional Application No. 60/912,178, filed on Apr. 17, 2007.

The disclosures of the above applications are incorporated herein by reference.

INTRODUCTION

The present teachings provide a patient-specific acetabular alignment guide and related instruments for guiding an acetabular implant into the acetabulum of a patient.

SUMMARY

The present teachings provide an acetabular device. In one aspect, the acetabular system includes a patient-specific acetabular alignment guide including a bone engagement surface. The bone engagement surface has a first portion configured and shaped to be conforming and complementary to an acetabular rim surface and a second portion configured and shaped to be conforming and complementary to a periacetabular area of an acetabulum of a patient. The acetabular alignment guide includes a plurality of guiding formations extending through the second portion for guiding a plurality of alignment pins therethrough. The bone engagement surface and the plurality of guiding formations are prepared from a three-dimensional model of the acetabulum of the specific patient reconstructed pre-operatively from a scan of the patient.

The acetabular device can also include an acetabular inserter including a handle, a shaft and an acetabular coupler and a first alignment adapter removably coupled to the shaft of the acetabular inserter. The first alignment adapter includes a plurality of apertures configured to correspond to the guiding formations of the acetabular alignment guide, such that the alignment pins can pass through the apertures of the alignment adapter after the acetabular alignment guide is removed without removing the alignment pins from the patient.

The present teachings also provide a method for inserting an acetabular implant into the acetabulum of a patient. The method includes engaging a patient-specific surface of the acetabular alignment guide to a complementary rim surface and periacetabular area of a patient and inserting a plurality of alignment pins through corresponding alignment apertures of the acetabular alignment guide and into the periacetabular area of the patient. The method further includes removing the acetabular alignment guide without removing the alignment pins from the patient, guiding a first alignment adapter coupled to an acetabular inserter over the alignment pins, and implanting the acetabular implant with the acetabular inserter.

The present teachings provide an acetabular device that includes an annular acetabular guide including a first surface and a second surface opposite to the first surface. The first surface is patient-specific and made to conform to an acetabular rim surface around an acetabulum of a patient in accordance with a three-dimensional image of the acetabulum of the patient. The acetabular guide includes a cylindrical inner guiding surface oriented at patient-specific anteversion and abduction angles relative to the first surface. The acetabular device also includes a patient-specific adapter having an outer surface mateable with the inner surface of the acetabular guide and having a quick-connection component for coupling to a non-custom acetabular instrument.

Further areas of applicability of the present teachings will become apparent from the description provided hereinafter. It should be understood that the description and specific examples are intended for purposes of illustration only and are not intended to limit the scope of the present teachings.

BRIEF DESCRIPTION OF THE DRAWINGS

The present teachings will become more fully understood from the detailed description and the accompanying drawings, wherein:

FIG. **1** is an exemplary illustration of a patient in preparation of an acetabular implant procedure;

FIG. **1**A is a perspective view of an acetabular guide according to the present teachings, the acetabular guide shown in relation to a patient's anatomy;

FIG. **2** is an environmental perspective view of the acetabular guide of FIG. **1**A shown with an acetabular inserter holding an acetabular implant according to the present teachings;

FIG. **3** is a perspective view of the acetabular inserter and acetabular implant of FIG. **2**;

FIG. **3**A is a perspective environmental view of an acetabular implant illustrating rotation about an anatomic axis A during insertion according to the present teachings;

FIG. **3**B is a perspective environmental view of an acetabular implant illustrating rotation about an anatomic axis B during insertion according to the present teachings;

FIG. **4** is an exploded view of the acetabular inserter and acetabular implant of FIG. **3**;

FIG. **4**A is a perspective view of a modular reamer for use according to the present teachings;

FIG. **4**B is bottom plan view of a reamer head of the reamer of FIG. **4**A;

FIG. **4**C is a perspective view of a reamer driver of the reamer of FIG. **4**A;

FIG. **4**D is bottom plan view of a distal end of the reamer driver of FIG. **4**C;

FIG. **4**E is a perspective view of the modular reamer of FIG. **4**A shown assembled with a an adaptor for use according to the present teachings;

FIG. **4**F is top plan view of the adaptor of FIG. **4**E;

FIG. **4**G is bottom plan view of the adaptor of FIG. **4**E;

FIG. **4**H is an environmental view of an assembled of a reamer with a patient-specific adapter according to the present teachings;

FIG. **5** is a perspective environmental view of an exemplary acetabular alignment guide according to the present teachings;

FIG. **6** is a perspective environmental view of the acetabular alignment guide of FIG. **5** shown with a plurality of guiding pins;

FIG. **7** is a perspective environmental view illustrating inserting an acetabular cup with an instrument guided by the guiding pins of FIG. **6**;

FIG. **8** is a perspective environmental view of an exemplary acetabular implant;

FIG. **9** is a perspective view of an exemplary impactor according to the present teachings;

FIG. **10** is a perspective view of an exemplary offset impactor according to the present teachings;

FIG. **11**A is an environmental view of a patient-specific acetabular guide according to the present teachings;

FIG. **11**B is an environmental view of a reamer patient-specific adapter guided for reaming the acetabulum by alignment pins placed using the patient-specific acetabular guide of FIG. **11**A;

FIG. **11**C is an environmental view of a length scale for measuring a length of an implant, the scale guided by an alignment pin placed using the patient-specific acetabular guide of FIG. **11**A;

FIG. **12** is a perspective view of a reamer with a patient-specific adapter guided for reaming the acetabulum by alignment pins placed using the patient-specific acetabular guide of FIG. **11**A;

FIG. **13** is an environmental view of a patient-specific resurfacing femoral implant according to the present teachings;

FIG. **14**A is an environmental anterior view of a patient-specific femoral implant according to the present teachings; and

FIG. **14**B is an environmental anterior view of the femoral implant of FIG. **14**A.

DESCRIPTION OF VARIOUS ASPECTS

The following description is merely exemplary in nature and is in no way intended to limit the present teachings, applications, or uses.

The present teachings generally provide a patient-specific acetabular guide and associated inserter for use in orthopedic surgery, such as in joint replacement or revision surgery, for example. The patient-specific alignment guides can be used either with conventional or patient-specific implant components prepared with computer-assisted image methods. Computer modeling for obtaining three dimensional images of the patient's anatomy using MRI or CT scans of the patient's anatomy, the patient-specific prosthesis components, and the patient-specific guides and templates can be provided by various CAD programs and/or software available, for example, by Materialise USA, Ann Arbor, Mich.

Patient-specific alignment guides and implants are generally configured to match the anatomy of a specific patient. The patient-specific alignment guides are generally formed using computer modeling based on the patient's 3-D anatomic image and have an engagement surface that is made to conformingly contact and match a three-dimensional image/model of the patient's bone surface (with or without cartilage or other soft tissue), by the computer methods discussed above. The patient-specific alignment guides can include custom-made guiding formations, such as, for example, guiding bores or cannulated guiding posts or cannulated guiding extensions or receptacles that can be used for supporting or guiding other instruments, such as drill guides, reamers, cutters, cutting guides and cutting blocks or for inserting pins or other fasteners according to a surgeon-approved pre-operative plan. The patient-specific alignment guides can be used in minimally invasive surgery, and in particular in surgery with multiple minimally-invasive incisions. Various alignment guides and pre-operative planning procedures are disclosed in commonly assigned and co-pending U.S. patent application Ser. No. 11/756,057, filed on May 31, 2007; U.S. patent application Ser. No. 12/211,407, filed Sep. 16, 2008; U.S. patent application Ser. No. 11/971,390, filed on Jan. 9, 2008, U.S. patent application Ser. No. 11/363,548, filed on Feb. 27, 2006; and U.S. patent application Ser. No. 12/025,414, filed Feb. 4, 2008. The disclosures of the above applications are incorporated herein by reference.

As disclosed, for example, in above-referenced U.S. patent application Ser. No. 11/756,057, filed on May 31, 2007; in the pre-operative planning stage for a joint replacement or revision procedure, an MRI scan or a series of CT scans of the relevant anatomy of the patient, such as, for example, the entire leg of the joint to be reconstructed, can be performed at a medical facility or doctor's office. The scan data obtained can be sent to a manufacturer. The scan data can be used to construct a three-dimensional image/model of the joint and provide an initial implant fitting and alignment in a computer file form or other computer representation. The initial implant fitting and alignment can be obtained using an alignment method, such as alignment protocols used by individual surgeons.

The outcome of the initial fitting is an initial surgical plan that can be printed or provided in electronic form with corresponding viewing software. The initial surgical plan can be

surgeon-specific, when using surgeon-specific alignment protocols. The initial surgical plan, in a computer file form associated with interactive software, can be sent to the surgeon, or other medical practitioner, for review. The surgeon can incrementally manipulate the position of images of implant components in an interactive image of the joint. Additionally, the surgeon can select or modify resection planes, types of implants and orientations of implant insertion. For example, the surgeon may select patient-specific anteversion and abduction angles for acetabular implants, as discussed below. After the surgeon modifies and/or approves the surgical plan, the surgeon can send the final, approved plan to the manufacturer.

After the surgical plan is approved by the surgeon, patient-specific alignment guides can be developed using a CAD program or other imaging software, such as the software provided by Materialise, for example, according to the surgical plan. Computer instructions of tool paths for machining the patient-specific alignment guides can be generated and stored in a tool path data file. The tool path can be provided as input to a CNC mill or other automated machining system, and the alignment guides can be machined from polymer, ceramic, metal or other suitable material, and sterilized. The sterilized alignment guides can be shipped to the surgeon or medical facility, for use during the surgical procedure.

The present teachings provide a patient-specific acetabular guide and associated inserter for inserting an acetabular implant in the acetabulum of a patient's pelvis in a guided orientation at least about first and second non-parallel anatomic axes. Referring to FIGS. **1**, **3**A and **3**B, the first anatomic axis indicated at "A", passes through the acetabulum **82** of a patient's pelvis **80** (only half of the pelvis is shown) and is oriented generally in a superior/inferior direction relative to the patient. The second anatomic axis is indicated at "B" and is substantially perpendicular to the first axis A. As described below, the present teachings provide instruments and methods for guiding, orienting and positioning an acetabular implant **200** at a selected angle of anteversion relative to the axis A, as shown in FIG. **3**A, and at a selected angle of abduction relative to the axis B, as also shown in FIG. **3**B. The anteversion and abduction angles can be determined interactive or other surgeon input and can be patient-specific.

Referring to FIG. **1**A, an exemplary acetabular guide **100** according to the present teachings can include a first surface **108** for engaging an area surrounding the acetabulum **82** and a second surface **110** opposite to the first surface **108**. The acetabulum-engaging first surface **108** can be custom-made or patient-specific to conform and mirror an acetabular rim surface **84** around the acetabulum **82** of a specific patient by using three-dimensional image or model of the acetabulum and surrounding pelvic area of the patient, as described above. The first surface **108** enables the acetabular guide to nest or closely mate relative to the acetabulum **82** of the patient.

The acetabular guide **100** can be temporarily and removably attached to the pelvis **80** using temporary fasteners **120**, such as bone nails or tacks, for example, passing through corresponding holes **104** through the acetabular guide **100**. The acetabular guide **100** can be annular with an opening defined by an inner surface **102**. The inner surface **102** can be, for example, a cylindrical surface. The inner surface **102** can be oriented relative to the first and second surfaces **108**, **110** of the acetabular guide **100** to provide a selected anteversion angle about the first axis A and a selected abduction angle relative to the axis B, as shown in FIGS. **2**, **3**A and **3**B. The anteversion and abduction angles can be surgeon-selected and patient-specific and can be determined with surgeon input during the pre-operative planning for the specific patient. Anteversion angles can be, for example, in the range of about 10-20 degrees forward relative to the first axis A, and adduction angles can be in the range of about 40-50 degrees downward relative to the second axis B.

Referring to FIGS. **2-4**, the acetabular guide **100** can be attached to the pelvis **80** around the acetabulum **72** after the acetabulum **82** has been reamed and prepared for receiving the acetabular implant **200**, such as the Magnum™ acetabular cup commercially available from Biomet, Inc., Warsaw, Ind. The acetabular implant **200** can be inserted into the prepared acetabulum **82** using an inserter **300** according to the present teachings. The inserter **300**, which can also function as an impactor, can include a handle **304** with a proximal impaction surface **318**, a shaft **302** and a guide-engaging portion **310** having a surface with a flat or planar portion **320**. The guide-engaging portion **310** can have an outer surface **312**, which conforms to and is mateable with the inner surface **102** of the acetabular guide **100** for guiding the acetabular implant **200**. The inner surface **102** and the outer surface **312** can be cylindrical.

Referring to FIG. **4**, the inserter **300** can engage the acetabular implant **200** via an intermediate member **250**, such as the intermediate member of the Magnum™ system, which is commercially available from Biomet, Inc., Warsaw, Ind. More specifically, the inserter **300** can include a distal portion **314**, such as a ball-bearing bushing, which can be inserted and engage a receptacle **252** of the intermediate member **250**. The acetabular implant **200** can be mounted on the inserter **300** by aligning a plurality of fingers **254** of the intermediate member **250** with corresponding cut-outs **202** on a peripheral edge of the acetabular implant **200**. The acetabular implant **200** can be secured to the inserter **300** by rotating the acetabular implant **200** relative to the insert **300** until a hand-tight fit is obtained.

Referring to FIG. **2**, the inserter **300** with the acetabular implant **200** mounted thereon can be directed toward the acetabular guide **100**. The outer surface **312** of the guide engaging portion **310** of the inserter **300** can be brought into contact with the inner surface **102** of the acetabular guide **100**, guiding the acetabular implant **200** toward the selected anteversion and abduction orientation through the acetabular guide **100**. The outer surface **312** of the guide engaging portion **310** can also provide an impaction-depth feedback by alignment with the inner surface **102** of the acetabular guide. Full impaction of the acetabular implant **200** into the acetabulum **82** can be indicated when planar portion **320** and/or outer surface **312** of the guide-engaging portion **310** of the inserter **300** are flush with and do not protrude over and above the second surface **110** of the acetabular guide **100**. Depth indicia **322** can also be provided on the inserter shaft **302** or on the guide-engaging portion **310** of the inserter **300**, as shown in FIG. **2**.

After the acetabular implant **200** is fully seated in the acetabulum **82** in the selected anteversion and abduction orientations, the inserter **300** and intermediate member **250** can be removed. The temporary fasteners **120** can be removed and the acetabular guide released.

The acetabular guide **100** can be made of any biocompatible material, such as metal, ceramic or polymer. The acetabular guide **100** can be constructed by various manufacturing methods depending of the selected material, including, for example, machining, casting, molding, stereolithography or other layer deposition methods. In one aspect, the acetabular guide **100** can be made of disposable plastic material.

The patient-specific acetabular guide **100** can also be used with a standard (non patient-specific) modular reamer **331** fitted with a patient-specific reamer adapter **360** to ream the

acetabulum of the specific patient in pre-planned patient-specific orientations. This allows the acetabular implant **200** to be received in the selected anteversion and abduction orientations, as shown in FIG. **4**H and discussed in connection with FIGS. **4**A-**4**H.

FIGS. **4**A-**4**C illustrate an exemplary modular reamer **331** that includes a reamer driver **330** and a reamer head **350**. The reamer driver **330** can be removably coupled to the reamer head **350** with a connecting mechanism **335**, which can be a spring-loaded, or snap-fit or other type of releasable connection, including connections secured with a set screw or other easily removable fasteners. An exemplary quick-connect connection is illustrated in FIGS. **4**A-**4**D and is also used to connect the reamer **331** to the reamer adapter **360**, as illustrated in FIGS. **4**E-**4**H.

The reamer head **350** can be in the form of a hollow cup with a semi-spherical reaming surface **353** bounded by a periphery **351**. The reaming surface **353** defines a plurality of reaming formations or reaming teeth **357**. A number of arms or rods **342** can be connected to the periphery **351** and form a first component of the quick-connect mechanism **335**. The arms **342** can be attached to one another at a central hub **341** forming a frame **343**, as shown in FIG. **4**B.

The reamer driver **330** can include a handle or sleeve **332** receiving a driver shaft **334** for coupling to a driver tool at a proximal end (not shown) and having a distal connector **338**. The distal connector **338** forms a second component of the quick connect mechanism **335**, which is operated with a spring-loaded slider or trigger **336** coupled to the driver shaft **334**. The distal connector **338** can include a number of openings or slots **344** and a corresponding number of movable or retractable pins **346**. The number of slots **344** corresponds to the number of arms **342** and the slots **344** are sized and shaped to receive the arms **342**. Although four arms, slots and pins are illustrated, a smaller or greater number can be used, for example two or three arms, slots and pins that can be evenly positioned radially about the reamer head **350**. To connect the reamer driver **330** to the reamer head **350**, the slots **344** are placed over the arms **342** with the pins **344** in their retracted position. The pins **344** can be retracted by moving the slider **336** in a direction away from the distal connector **338**. When the slider **336** is released, the arms **342** are gripped between the pins **344** and the walls of the slots **344** and the reamer driver **330** is securely connected to the reamer head **350**.

Referring to FIGS. **4**E-**4**H, the patient-specific reamer adapter **360** can include can include a first portion **362** and a second portion **368**. The first portion **362** can have an outer surface **364**. The outer surface **364** can be, for example, cylindrical. The outer surface **364** can be shaped, sized and oriented to mate with the inner surface **102** of the patient-specific guide **100** to provide a selected and patient-specific anteversion angle about the first axis A and a selected abduction angle relative to the axis B, as shown FIG. **4**H. In this respect, the outer surface **364** of the adapter **360** is patient specific.

The reamer adapter **360** can be coupled to the reamer with a quick-connect connection. For example, the reamer adapter **360** can be coupled between the reamer driver **330** and the reamer head **350** with corresponding components of the quick-connect mechanism **335** used for the connecting the reamer driver **330** to the reamer head **350**. Referring to FIGS. **4**E-**4**H, the first portion **362** can include a number of arms **370** coupled to a proximal periphery **363** of the first portion **262** and are configured to engage the distal connector **338** of the reamer driver **330**, i.e. to be gripped in corresponding slots **344** by corresponding pins **346**. In this regard, the arms **370** of the first portion **362** provide a component that is complementary to the quick-connect component of the reamer driver **330** and complete a quick-connect mechanism **335** between the reamer drier **330** and the reamer adapter **360**.

Similarly, the second portion **368** of the reamer adapter **360** can include a quick-connect component complementary to the quick-connect component of the reamer head **350** to complete the quick-connect mechanism **335**. More specifically, the second portion **368** can include a number of slots **374** and pin **372** for gripping the arms **342** of the reamer head **350**. Accordingly, the same type of quick-connect mechanism **335** that is used to couple the reamer driver **330** to the reamer head **350** can be used to couple the reamer adapter **360** between the reamer driver **330** and the reamer head **350**, as illustrated in FIGS. **4**A and **4**E. It is noted that the quick-connect mechanism **335** is not limited to the exemplary embodiment illustrated, but can be any quick-connect mechanism used for non-patient-specific modular reamers, include snap-fit, tapered connectors, threaded connectors, or any other connectors with complementary components "a" for the reamer driver **330** and "b" for the reamer head **350**, which are then used in reverse order to couple the reamer adapter **360** therebetween in a sequence a-b-a-b. In the illustrated quick-connect mechanism **335**, component "a" includes slots and pins and component "b" includes arms.

Referring to FIG. **4**H, the assembled reamer **331** with the patient-specific adapter **360** can be used with the patient-specific acetabular guide **100** to ream the acetabulum **82** of the patient to receive an implant in a selected patient-specific orientation according to the pre-operative plan. As described above in relation to FIGS. **1-4**, the acetabular guide **100** is attached to the acetabulum **82** in only one position, such that the inner surface **102** provides an orientation guide for the reamer head **350**. In particular, the outer surface **364** of the reamer adapter **360** mates in a complementary close-fit manner with the inner surface **102** of the acetabular guide **100**, such that the reamer head **350** can be oriented as specified in the pre-operative plan to ream the acetabulum in the selected anteversion and abduction orientations relative to the corresponding axes A and B. After the acetabulum **82** is reamed, the acetabular implant **200** can be impacted in the same selected orientation using the inserter/impactor **300** discussed in connection with FIGS. **2** and **3**.

The exemplary acetabular guide **100** illustrated in FIGS. **1**A, **2** and **4**H is annular for placement around the acetabulum **82**. In other embodiments, an acetabular guide **400** positioned only in a portion around the acetabulum **82** can also be used. Referring to FIGS. **5-10**, the patient-specific acetabular alignment guide **400** and other instruments for guiding an acetabular implant are illustrated. The patient-specific acetabular alignment guide **400** can be prepared during a pre-operative plan for the surgical procedure based on a three-dimensional image of the relevant anatomy of the patient including portions of the pelvis **80**, the acetabulum **82**, the acetabular rim area **84**, the periacetabular area and generally the hip joint of the patient. The three-dimensional image of the anatomy of the patient can be developed by commercially available software, as discussed above, using MRI, CT, X-rays or other scans of the particular patient.

Referring to FIGS. **5** and **6**, the acetabular alignment guide **400** can include a first portion **402** configured and adapted to be positioned around the rim surface **84** of the acetabulum **82** and a second portion **404** configured and adapted to be positioned around the periacetabular area of the pelvis **80** of a specific patient. The acetabular alignment guide **400** can include a three-dimensional curved patient-specific bone engagement surface **408**. The bone engagement surface **408** is defined to match complementarily to a portion of the

acetabular rim surface **84** and a portion of an adjacent periacetabular area of the pelvis **80** of the patient for close contact/nesting thereon in only one position and orientation. The second portion **404** of the acetabular alignment guide **400** is designed during the pre-operative plan to define a plurality of elongated through-slots, apertures or other guiding formations **406** directed toward the periacetabular area for guiding a plurality of alignment pins **420** parallel to an acetabular centering axis CC, the location and orientation of which is determined according to the preoperative plan for the specific patient. The second portion **404** can be reinforced with additional materials and/or have thicker dimensions for stability.

Three guiding formations **406** in the form of through holes and a corresponding number of alignment pins **420** are illustrated in FIGS. **5** and **6**. Depending on the patient and/or procedure, a different number of guiding formations **406** and alignment pins **420** can be used. The alignment pins **420** can be parallel defining a patient specific orientation and operable for locating the acetabular centering axis CC. The alignment pins **420** can removably guide along the same axis other instruments associated with the insertion of an acetabular implant **200** after the acetabular alignment guide **400** is removed, as shown in FIG. **7**, for example. The orientation and location of the guiding formations **406** can be patient-specific and determined pre-operatively to facilitate guiding and supporting the various instruments used for positioning, inserting and impacting the acetabular implant **200**, as discussed below.

Referring to FIG. **7**, after the alignment pins **420** have been inserted into the bone, the acetabular alignment guide **400** can be removed. An acetabular positioner or inserter or inserter/impactor **450** can be guided by the alignment pins **420** for inserting the acetabular implant **200** in the acetabulum. The inserter **450** can include a handle **451** with a knob **453** and a shaft **452** coupled to a patient-specific alignment adapter **470**. The patient-specific alignment adapter **470** can include an arm **474** defining a plurality of alignment apertures **478** complementary to the alignment pins **420**, such that the alignment adapter **470** can removably slide over the alignment pins **420**. In this respect, the shape and size of the arm **474** and the placement, arrangement and configuration of the alignment apertures **478** can be determined during the pre-operative plan to correspond to the guiding formations **406** of the acetabular alignment guide **400**. The alignment adapter **470** can include a coupling opening **472** for removably receiving the shaft **452** of the inserter **450** or can be integrally coupled to the shaft **452** of the inserter **450**. The coupling opening **472** can be, for example, an interference fitting or snap-on side slot. Alternatively, the coupling opening **472** can be an enclosed hole, which receives the shaft **452** of the inserter **450**, when the shaft is modularly coupled to the inserter **450**. The inserter **450** can be connected to and disconnected from the acetabular implant **200** with a coupler **480** at the distal end of the shaft **452** by rotating the knob **453**. The coupler **480** can also be modularly connected to the shaft **452**. During insertion of the acetabular implant **200**, the alignment pins **420** help stabilize, guide and secure the orientation of the inserter/impactor **450** and acetabular implant **200** and place the acetabular implant **220** in the desired position and orientation relative to the acetabulum **82** as determined during the pre-operative plan using imaging scans of the patient.

Similar patient-specific alignment adapters **470** can be used for guiding other type of inserters or impactors or reamers with reamer driver handles or other instruments, such as, for example, reamers and impactors that can be used during the preparation and implantation procedure. Referring to FIGS. **9** and **10**, first and second impactors (or other acetabular instruments) **500***a*, **500***b* are illustrated with respective first and second patient-specific alignment adapters **470***a*, **470***b*. The first impactor **500***a* is an offset impactor **500***a* generally used for minimally invasive procedures, and the second impactor **500***b* is straight, non-offset impactor. Each of the first and second impactors **500***a*, **500***b* can be modular and include a handle **502** respectively coupled to a first shaft **504***a* or second **504***b* terminating at a coupler **510** with an end connector **512**. The first shaft **504***a* of the first impactor **500***a* is offset relative to a longitudinal axis C (designed to coincide with the acetabular centering axis CC) passing through the handle **502** and the end connector **512**. The shaft **504***b* of the second impactor **500***b* is coaxial with the handle **502**.

As illustrated in FIG. **9**, the offset first shaft **504***a* can include a center portion **505***c* offset and substantially parallel to the longitudinal axis C and first and second end portions **505***a*, **505***b* angled relative to the center portion **505***c* for defining the offset. The first end portion **505***a* can be cannulated or hollow for receiving a shaft **492** of a driver **490** coupled to the end connector **512**, such that the end connector **512** can be secured to the acetabular implant **200** by rotating a knob **494** of the driver **490**. The first alignment adapter **470***a* includes a coupling opening **472** (enclosed hole or side opening/slot) through which the portion **505***a* can pass through. As discussed above in connection with alignment adapter **470** and the inserter **450** of FIG. **7**, the shape and size of the arm **474** and the placement and arrangement/configuration of the alignment apertures **478** can be determined during the pre-operative plan to correspond to the guiding formations **406** of the acetabular alignment guide **400** and the location and orientation of the alignment pins **420**, such that the parallel alignment pins **420** can pass through the parallel alignment apertures **478** to guide the first impactor **500***a* relative to the acetabular implant **200** and relative to the acetabulum **82**. The first alignment adapter **470***a* can be removably coupled to the first impactor **500***a* and can be slidably adjusted in position relative to the first portion **505***a* while maintaining the alignment orientation of the alignment apertures **406** relative to axis CC and the alignment pins **420**.

Referring to FIG. **10**, the second impactor **500***b* can be used similarly. Because the shaft **504***b* is substantially straight (not offset), the end connector **512** can be attached to the acetabular implant **200** by simply rotating the handle **502** or a knob attached to the handle (not shown), similarly to the inserter **450** shown in FIG. **7**. Each impactor **500***a*, **500***b* can be modular, such that the handle **502**, the shaft **504***a*, **504***b* and/or the coupler **510** can be disassembled for removably mounting the alignment adapter **470***a*, **470***b*. Additionally, or alternatively, the coupling opening **472** can be a snap-on side opening or side slot for removably receiving the alignment adapter **470***a*, **470***b* without disassembling the impactor **500***a*, **500***b*.

In some embodiments, the same alignment adapter can be used for more than one conventional acetabular instrument. For example, the same the alignment adapter **470** (or **470***b*) can be used optionally either with the inserter/impactor **450** or the impactor **500***b*, or with an acetabular reamer, such as reamer **331**.

It will be appreciated from the above discussion, that although the patient-specific acetabular alignment guide **400** has an engagement surface **408** that is complementary to the acetabular/periacetabular area of the patient, the alignment adapters **470**, **470***a* and **470***b* may or may not have a patient-specific engagement surface as they are at a distance away from the bone surface during use. Rather, the location and arrangement of the alignment apertures **478** on the arm **474** is patient-specific, such that the corresponding alignment adapter **470**, **470***a*, **470***b* can be mounted over the plurality of

the alignment pins **420** that have been already secured around the acetabulum **82** of the patient using acetabular alignment guide **400**.

The acetabular alignment guide **400** and the alignment adapters **470**, **470***a*, **470***b* can be made of disposable polymeric materials or any other biocompatible materials. The alignment adapters **470**, **470***a*, **470***b* can be used with acetabular inserters, positioners, reamers, impactors and other instruments used during the acetabular procedure. The acetabular alignment guide **400** and one or more alignment adapters **470** can be provided in a form of a kit with a set of alignment pins **420**. Other reusable, non custom instruments can be also included, for example, an inserter, reamer impactor, etc. The kit can include an acetabular implant **200**, which can be custom-made or non custom-made, as approved and selected by the surgeon.

Referring to FIGS. **11**A to **12**, another patient-specific acetabular guide **400'** is illustrated for use with a reamer **331'**. As discussed above in connection with acetabular guides **100** and **400**, the acetabular guide **400'**, can include a first portion **402'** configured and adapted to be positioned around the rim surface **84** of the acetabulum **82** and a second portion **404'** configured and adapted to be positioned around the periacetabular area of the pelvis **80** of a specific patient. The acetabular alignment guide **400'** can include a three-dimensional curved patient-specific bone engagement surface **408'**, which is the underside surface of the first and second portions **402'**, **404'** that nestingly mates with the specific patient's anatomy. In the exemplary embodiment illustrated in FIG. **11**A, the first portion **402'** can extend around the entire inner rim surface **84** of the acetabulum and at least a portion of the acetabulum **82**. Similarly, the second portion **404'** can extend around the entire periacetabular area around the acetabulum **84** when additional stability and attachment area is desired for the particular patient or preferred by the surgeon. The bone engagement surface **408'** can be designed to match complementarily to portions of the acetabular rim surface **84**, of the acetabulum **82** and of an adjacent periacetabular area of the pelvis **80** of the patient for close contact/nesting thereon in only one position and orientation. The second portion **404'** of the acetabular alignment guide **400** is also designed during the pre-operative plan to define a plurality of elongated through-slots, apertures or other guiding formations or holes **406'** directed toward the periacetabular area for guiding a plurality of alignment pins **420** parallel to the pre-determined acetabular centering axis CC, as discussed above in connection with FIGS. **5-7**. After the alignment pins **620** are secured to the bone, the acetabular guide **400'** can be removed leaving the alignment pins **420** for use with a reamer, as discussed below.

A reamer **331'** or **331"** can be guided by the alignments pins **420**, as shown in FIGS. **11**B and **12**, respectively, along the acetabular centering axis CC. An off-the-shelf or standard (non custom) reamer **331'**, **331"** can be used in combination with an adjustable or a patient-specific adapter **470'**, **470"**. The adapter **470'** can include one or more arms **474'** (two arms **474'** are illustrated in FIG. **11**B). Each arm **474'** can be coupled to a shaft **330'** of the reamer **431'** with a quick-coupling arrangement **474'**, which can be, for example, an opening in the arms configured for receiving the shaft **330'** or other coupler. Each arm **474'** can include at least one opening **478'** positioned and configured for receiving a corresponding alignment pin **420**, which is secured to the bone in a predetermined position and orientation using the patient-specific alignment guide **400'** through a corresponding hole **406** of the guide **400"**. Accordingly, the location and orientation of the openings **478'** on the arms **474'** and relative to the acetabular centering axis CC are patient-specific. In some embodiments, an arm **474'** can include more than one opening **478'**. The arms **474'** can be integrally attached to one another, or modularly or separately coupled to the shaft **330'**. One of the alignment pins, pin **420'** for example, can provide a fixed point of reference for measuring the length of the leg of the patient for determining the length of an implant **200'** and the depth in the corresponding intramedullary canal. The implant **200'** can include a head **203'** and a stem **201'**, as shown in FIG. **11**C. A scale or other measuring device **477** can be coupled to the pin **420'** for measuring the length and sizing the implant **200'**. The scale **477** can be slidably placed over the pin **477'** as shown in FIG. **11**B. The length can be measured before implantation and also-post implantation (as shown in FIG. **11**B) for confirming proper impaction and placement of the implant.

Referring to FIG. **12**, a non-custom reamer **331"** can be coupled with a patient-specific adapter **470"** designed to slide over the alignment pins **420**, after the alignment pins **420** are secured on the patient's pelvis **80** in a patient-specific configuration, position and orientation, which also determines the acetabular centering axis CC, as discussed above in connection with FIGS. **5-7**. In the embodiment illustrated in FIG. **12**, the adapter **470"** can be monolithic and include two arms **474"** for receiving respectively two alignment pins **420** through corresponding openings **478"**, although different number of arms **474"** can be used and each arm **474"** can include more than one opening **478"** for receiving more than one pin **420**. The adapter **470"** can by coupled to the reamer **331"** with a quick-connect to the shaft of the reamer **331"**, as described above in relation to FIGS. **4**A-**4**G, or with another type of connection **335"**, such as snap-fit or threadable socket or bayonet coupling. The reamer **331"** can be of the blade type, including reaming blades **333"**. In one embodiment, the blades **333"** can be removable, replaceable and/or disposable. Each blade **333"** can be semicircular or quarter-circular and can be attached to a chuck or other support **337"** of the reamer **331"** with set screws or grooves or jaws.

In some procedures, the acetabular implant **200** discussed above can be used to articulate with a patient-specific resurfacing or replacement proximal femoral component, as shown in FIGS. **13**, **14**A and **14**B. For example, a patient-specific resurfacing implant can be designed during the pre-operative plan based on image models reconstructed from scans of the patient.

Referring to FIG. **13**, when the femoral head **92** is salvageable and need not be resected and replaced, the diseased or defective surface of the femoral head **92** can be identified in the image. A femoral component **600** can be designed to replace the defective portions, such as poor bone quality and/or avascular regions of the femoral head **92**. The femoral component **600** can include a dome-shaped portion or dome **602** with an outer convex articulating surface **603** for articulating with an acetabular implant or the patient's natural acetabulum and an inner bone engagement surface **604** that is designed to match and be complementary and match the surface of the femoral head **92** with or without soft tissue attached, as determined in the pre-operative plan. The dome **602** can have a periphery **608** designed such that the dome covers and resurfaces all the defective portions of the femoral head **92**. The femoral component **600** can have a short stem **606**, which is inserted through the femoral head **92** and secured into the femoral neck **94**. The stem **606** can be designed during the preoperative plan based on the theedimensional reconstruction of the patient's anatomy from the patient's scans such that the axis of the stem D is placed in a selected position and orientation relative to the neck **94** of the patient's and in a selected anteversion orientation relative to

the proximal femur **90**. Additionally, the length of the stem **606** and the size and shape of the cross-section **607** along the length of the stem **606** can also be designed based on the preoperative plan and the reconstruction model of the neck **94** of the patient, such that bone preservation and adequate attachment support are balanced and/or optimized for the particular patient.

Referring to FIGS. **14**A and **14**B, a patient-specific femoral implant **618** for a proximal femur in which the femoral head **92** is resected can include a femoral head component **620**, a femoral neck component **624** and a femoral stem component **622**. The femoral implant **618** can be designed during the preoperative plan based on the thee-dimensional reconstruction of the patient's anatomy from the patient's scans such that the femoral head implant **620** and femoral neck component **624** cooperate to retain the axis D and the center of rotation R of the patient's femur or acetabulum, based on surgeon determination and preference. The femoral neck component **624** can be designed to match the patient's femoral neck **94** in size and orientation. The femoral stem implant **622** can be selected from standard (non custom) stem sizes) or can be customized for length, cross-section and/or shape for the specific patient.

The foregoing discussion discloses and describes merely exemplary arrangements of the present teachings. Furthermore, the mixing and matching of features, elements and/or functions between various embodiments is expressly contemplated herein, so that one of ordinary skill in the art would appreciate from this disclosure that features, elements and/or functions of one embodiment may be incorporated into another embodiment as appropriate, unless described otherwise above. Moreover, many modifications may be made to adapt a particular situation or material to the teachings of the invention without departing from the essential scope thereof. One skilled in the art will readily recognize from such discussion, and from the accompanying drawings and claims, that various changes, modifications and variations can be made therein without departing from the spirit and scope of the present teachings as defined in the following claims.

What is claimed is:

1. An acetabular system comprising:

a patient-specific acetabular alignment guide including a bone engagement surface having first and second portions, the first portion configured and shaped to be conforming and complementary only to a portion of a rim surface around an acetabulum of a specific patient without extending into the acetabulum, and the second portion configured and shaped to be conforming and complementary to a periacetabular area outside the acetabulum of the specific patient in accordance with a three-dimensional model of the acetabulum of the specific patient reconstructed pre-operatively from an image scan of the patient, the acetabular alignment guide including a plurality of guiding formations extending through the second portion for guiding a plurality of alignment pins therethrough, wherein the plurality of guiding formations are arranged and configured based on a pre-operative plan for the patient.

2. The acetabular system of claim **1**, further comprising a patient-specific alignment adapter couplable to an acetabular instrument, the alignment adapter including a plurality of apertures configured to correspond to the guiding formations of the acetabular alignment guide for sliding over the corresponding alignment pins.

3. The acetabular system of claim **2**, wherein the plurality of guiding formations includes three guiding bores and the plurality of apertures of the patient-specific alignment adapter includes three corresponding apertures.

4. The acetabular system of claim **2**, wherein the guiding formations are parallel guiding bores.

5. The acetabular system of claim **4**, further comprising an acetabular inserter, the acetabular inserter including a shaft passing through a snap-on side opening of the alignment adapter.

6. The acetabular system of claim **4**, further comprising an acetabular inserter, the acetabular inserter including a shaft removably coupled to the alignment adapter and parallel to the guiding bores.

7. The acetabular system of claim **4**, further comprising an acetabular impactor, the impactor including a shaft removably coupled to the alignment adapter and having a handle that is offset relative to a central portion of the shaft of the impactor.

8. The acetabular system of claim **4**, wherein the patient-specific alignment adapter has a patient-specific surface and is slidable relative to the acetabular instrument.

9. An acetabular system comprising:

a patient specific acetabular alignment guide including a bone engagement surface configured and shaped to be conforming and complementary to an acetabular and periacetabular area of an acetabulum of a specific patient in accordance with a three-dimensional model of the acetabulum of the specific patient and based on a pre-operative plan, the acetabular alignment guide including a plurality of guiding formations extending therethrough for guiding a plurality of alignment pins in a periacetabular area of a patient;

an acetabular instrument including a handle, a shaft and an acetabular coupler; and

a first alignment adapter removably coupled to the shaft of the acetabular instrument, the first alignment adapter including a plurality of apertures configured to correspond to the guiding formations of the acetabular alignment guide, such that the alignment pins can pass through the apertures of the alignment adapter after the acetabular alignment guide is removed without removing the alignment pins from the patient.

10. The acetabular system of claim **9**, wherein the shaft of the acetabular instrument is removably inserted through a coupling opening of the first alignment adapter.

11. The acetabular system of claim **10**, wherein the coupling opening is a snap-on side opening.

12. The acetabular system of claim **9**, further comprising a second acetabular instrument having a shaft removably couplable to the first alignment adapter.

13. The acetabular system of claim **9**, further comprising:

an acetabular impactor having a handle and a shaft offset from the handle; and

a second alignment adapter removably coupled to the shaft of the acetabular impactor, the second alignment adapter including a plurality of apertures complementary to the guiding formations of the acetabular alignment guide, such that the alignment pins can pass through the apertures of the second alignment adapter after the acetabular alignment guide is removed without removing the alignment pins from the patient.

14. The acetabular system of claim **13**, wherein the shaft of the acetabular impactor is removably inserted through a coupling opening of the second alignment adapter.

15. The acetabular system of claim **14**, wherein the coupling opening is a snap-on side opening.

16. The acetabular system of claim **14**, wherein the impactor is modular.

17. The acetabular system of claim **9**, further comprising an acetabular implant.

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UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 8,603,180 B2
APPLICATION NO. : 13/111007
DATED : December 10, 2013
INVENTOR(S) : John R. White et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Title Page 9, References Cited, Other Publications, Column 2, line 51, (Information Disclosure Statement dated July 8, 2011, Form 1449, page 19, Non Patent Literature Documents, Reference No. CI2), Delete "Arthuroplasty" and insert --Arthroplasty--.

In the Specification
Column 3, Line 29; After "with", delete "a".
Column 6, Line 34; Delete "insert" and insert --inserter--.
Column 7, Line 39; Delete "insert" and insert --inserter--.
Column 7, Line 40; Delete "344" and insert --346--.
Column 7, Line 43; Delete "344" and insert --346--.
Column 7, Line 46; After "360", delete "can include".
Column 7, Line 53; After "shown", insert --in--.
Column 7, Line 63; Delete "262" and insert --362--.
Column 8, Line 3; Delete "drier" and insert --driver--.
Column 9, Line 59; Delete "220" and insert --200--.
Column 10, Line 3; After "impactor", delete "500a".
Column 10, Line 8; After "second", insert --shaft--.
Column 10, Line 38; Delete "406" and insert --478--.
Column 11, Line 13; After "reamer", insert --,--.
Column 11, Line 34; Delete "84" and insert --82--.
Column 11, Line 47; Delete "620" and insert --420--.
Column 12, Line 12; Delete "477'" and insert --420'--.
Column 12, Line 13; Delete "FIG. 11B" and insert --FIG. 11C--.
Column 12, Line 14; Delete "also-post implantation" and insert --also post-implantation--.
Column 12, Line 14; Delete "FIG. 11B" and insert --FIG. 11C--.
Column 13, Line 21; Delete "sizes)" and insert --sizes--.

Signed and Sealed this
Seventh Day of October, 2014

Michelle K. Lee

Michelle K. Lee
Deputy Director of the United States Patent and Trademark Office